

# **SAMSUNG BIOEPIS**

Biosimilar Market Dynamics

**8<sup>th</sup> Edition, Q1 2025**

# | FOREWORD

Dear colleagues,

As we step into a new year, it's incredible to reflect on how far we have come in the US biosimilar market. This marks the third year since the launch of the Samsung Bioepis biosimilar report. Over the years, our commitment to providing valuable insight and staying ahead of market trends has only grown stronger as the market rapidly evolves.

This year, the industry is set to witness the launch of biosimilars in new therapeutic areas and new molecules such as eculizumab, aflibercept, ustekinumab, and denosumab. We are eager to track the market movements that they will generate. In closing, we look forward to continuing to deliver a comprehensive analyses that supports informed evaluations in the ever-evolving US market biosimilar landscape.

Wishing you a prosperous and successful year ahead!

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**Thomas Newcomer**

Vice President

Head of Market Access, Samsung Bioepis US



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# I. US Biosimilars Approval & Launch Status

US Biosimilars Approval & Launch Status

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

Reference

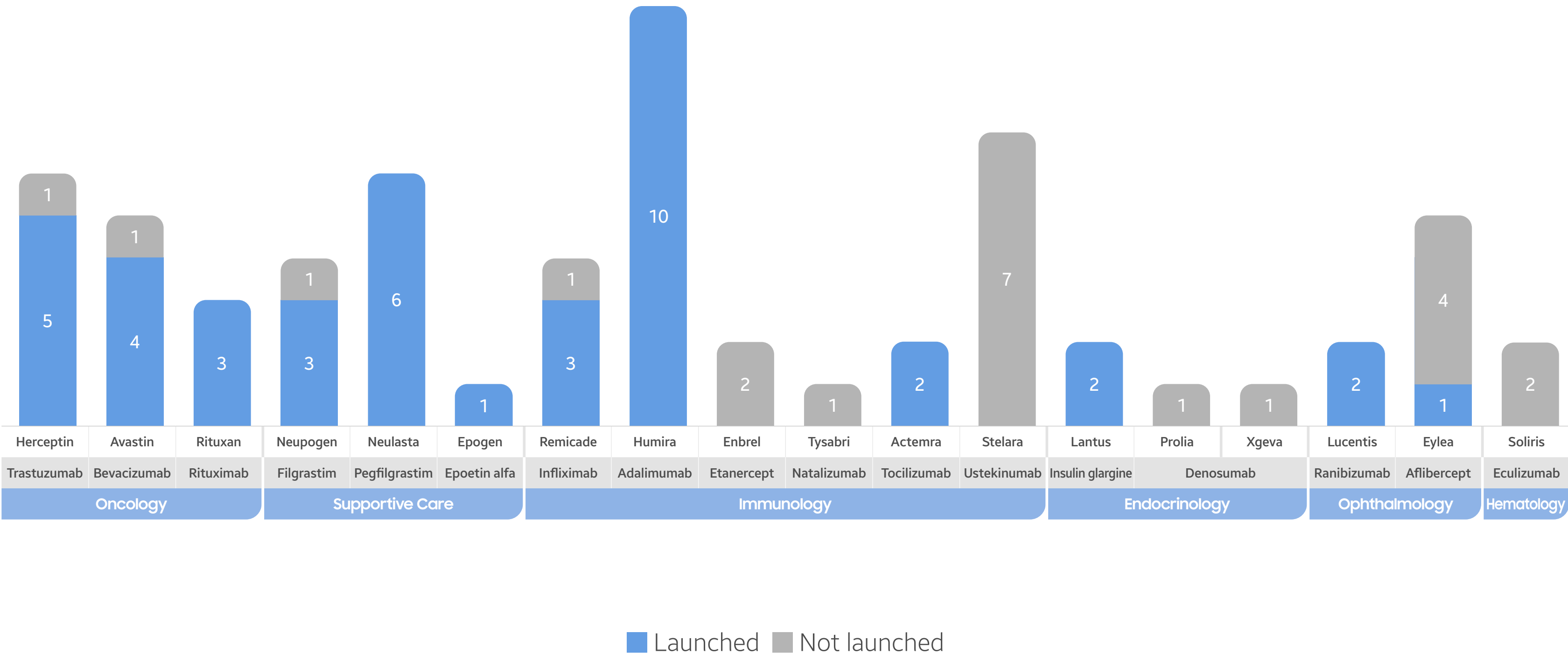
# FDA Approval and Launch Status of US Biosimilars

- ✦ As of Dec 2024, the FDA has approved a total of 64 biosimilars across 17 unique biological molecules. Of the 64 approvals, 41 biosimilars have launched in the US market.
- ✦ In last quarter, three new biosimilars were approved in the US. (See Figure 2, 2-1)
  - Imuldosa, Yesintek, Steqeyma for Stelara (ustekinumab) biosimilar

Cumulative Approvals

64

Figure 1. Biosimilars Approval and Launch Status in the US<sup>1\*</sup> (As of Dec 2024)



FDA: Food and Drug Administration  
<sup>1</sup>Trade marks are not described to all brands

US Biosimilars Approval & Launch Status

Biosimilar Price – Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price – Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
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- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

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Figure 2. Biosimilars Approval and Launch Status in the US<sup>1\*</sup> (As of Dec 2024, with Suffix)

TA	Oncology			Supportive Care			Immunology					
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Neupogen (filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbvVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009
Biosimilar	Ogivri (trastuzumab-dkst) Biocon 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx ) Hospira&Pfizer 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szsz) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Biogen&Bio-Thera 2023	Wezlana (ustekinumab-auub) Amgen 2023
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018		Renflexis (infliximab-abda) Samsung Bioepis&Organon 2017	Cyltezo (adalimumab-adbm) Boehringer Ingelheim 2017	Eticovo (etanercept-ykro) Samsung Bioepis 2019		Tyenne (tocilizumab-aazg) Fresenius Kabi 2024	Selarsdi (ustekinumab-aekn) Alvotech&Teva 2024
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019		Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018				Pyzchiva (ustekinumab-ttwe) Samsung Bioepis&Sandoz 2024
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (bevacizumab-adcd) Celltrion 2022		Nypozi (filgrastim-txid) Tanvex 2024	Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019				Otulfı (ustekinumab-aauz) Formycon&Fresenius Kabi 2024
	Kanjinti (trastuzumab-anns) Amgen 2019	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019				Imuldosa (ustekinumab-srif) Dong-A ST&Meji Seika &Accord Biopharma 2024
	Hercessi (trastuzumab-strf) Accord BioPharma&Henlius 2024				Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Biocon 2020				Yeintek (ustekinumab-kfce) Biocon 2024
								Yusimry (adalimumab-aqvh) Meitheal 2021				Steqeyma (Ustekinumab-stba) Celltrion 2024
								Idacio (adalimumab-aacf) Fresenius Kabi 2022				
								Yuflyma (adalimumab-aaty) Celltrion 2023				
								Simlandi (adalimumab-ryvk) Alvotech&Teva 2024				

■ Launched   ■ Not launched

<sup>1</sup>Trade marks are not described to all brands

Continued on next page →

US Biosimilars Approval & Launch Status

Biosimilar Price – Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price – Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
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- Ophthalmology

Biosimilar Deep Dive

Reference

Figure 2–1. Biosimilars Approval and Launch Status in the US<sup>1\*</sup> (As of Dec 2024, with Suffix)

TA	Endocrinology		Ophthalmology		Hematology/Nephrology
Molecule	Denosumab	Insulin glargine	Ranibizumab	Aflibercept	Eculizumab
Reference Product	Prolia/Xgeva (denosumab) Amgen 2010	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006	Eylea (aflibercept) Regeneron 2011	Soliris (eculizumab) Alexion 2007
Biosimilar	Jubbonti/Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfgn) Biocon 2021	Byooviz (ranibizumab-nuna) Samsung Bioepis&Biogen 2021	Opuviz (aflibercept-yszy) Samsung Bioepis&Biogen 2024	Bkemv (eculizumab-aeeb) Amgen 2024
		Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Cimerli (ranibizumab-eqrn) Sandoz 2022	Yesafili (aflibercept-jbvf) Biocon 2024	Epysqli (eculizumab-aagh) Samsung Bioepis 2024
				Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024	
				Enzeevu (aflibercept-abzv) Sandoz 2024	
				Pavblu (aflibercept-ayyh) Amgen 2024	

Launched Not launched

<sup>1</sup>Trade marks are not described to all brands



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## II. Biosimilar Price

### (Medical Benefit & Pharmacy Benefit)

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Biosimilar Price – Medical Benefit

- Oncology
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- Immunology & Ophthalmology

Biosimilar Price – Pharmacy Benefit

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Market Share & Price Trends

- Oncology
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- Ophthalmology

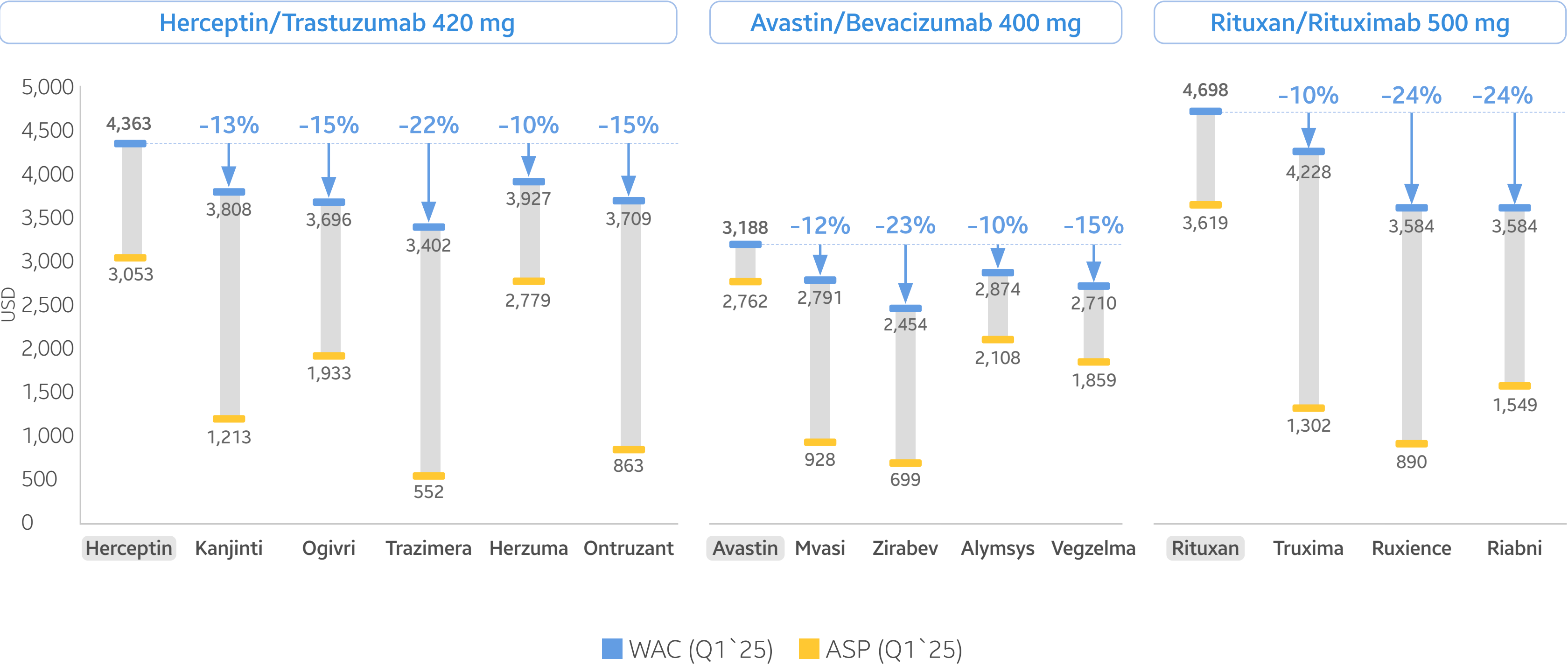
Biosimilar Deep Dive

Reference

# Oncology WAC and ASP – Q1 2025

- ✦ Across oncology biosimilars, WAC prices represent a modest discount (between 10-25%) compared to reference products.
- ✦ Q1 2025 Biosimilar ASP discounts as compared to the reference product ASP average -52%, -49%, and -66% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 3. Q1 2025 WAC and ASP<sup>2,3</sup>



Products are listed in order of launch  
ASP: Average Sales Price; WAC: Wholesale Acquisition Cost

Biosimilar Price – Medical Benefit

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Biosimilar Price – Pharmacy Benefit

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- Endocrinology
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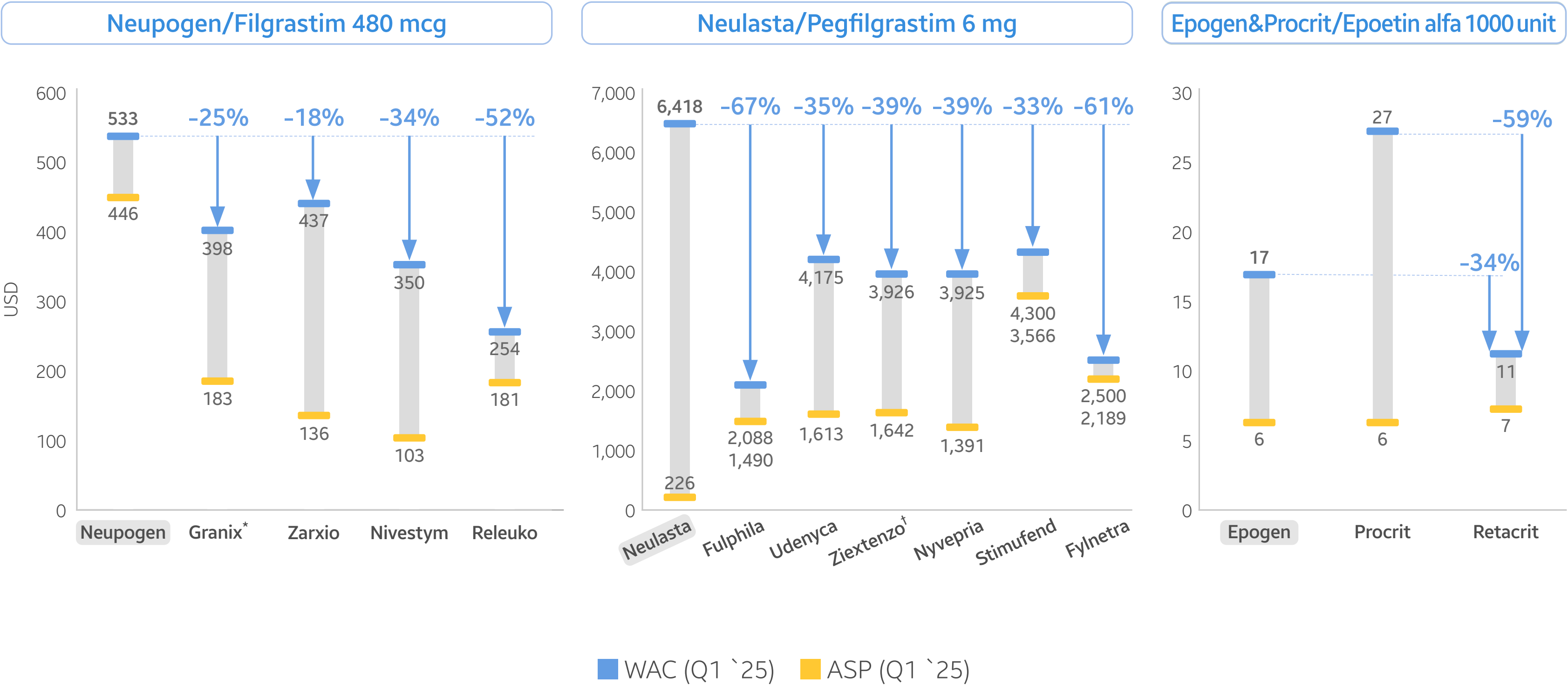
Biosimilar Deep Dive

Reference

# Supportive Care WAC and ASP – Q1 2025

- ✦ Across supportive care biosimilars, WAC price discounts range between 18-67% compared to reference products.
- ✦ Amgen, the manufacturer for originator filgrastim (Neupogen) and pegfilgrastim (Neulasta), only provides competitive ASP pricing in the pegfilgrastim market.

Figure 4. Q1 2025 WAC and ASP<sup>2,3</sup>



Products are listed in order of launch  
ASP: Average Sales Price; WAC: Wholesale Acquisition Cost  
\*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway † Ziextenzo ASP republished in Q1 2025

Biosimilar Price – Medical Benefit

- Oncology
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Biosimilar Price – Pharmacy Benefit

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Biosimilar Deep Dive

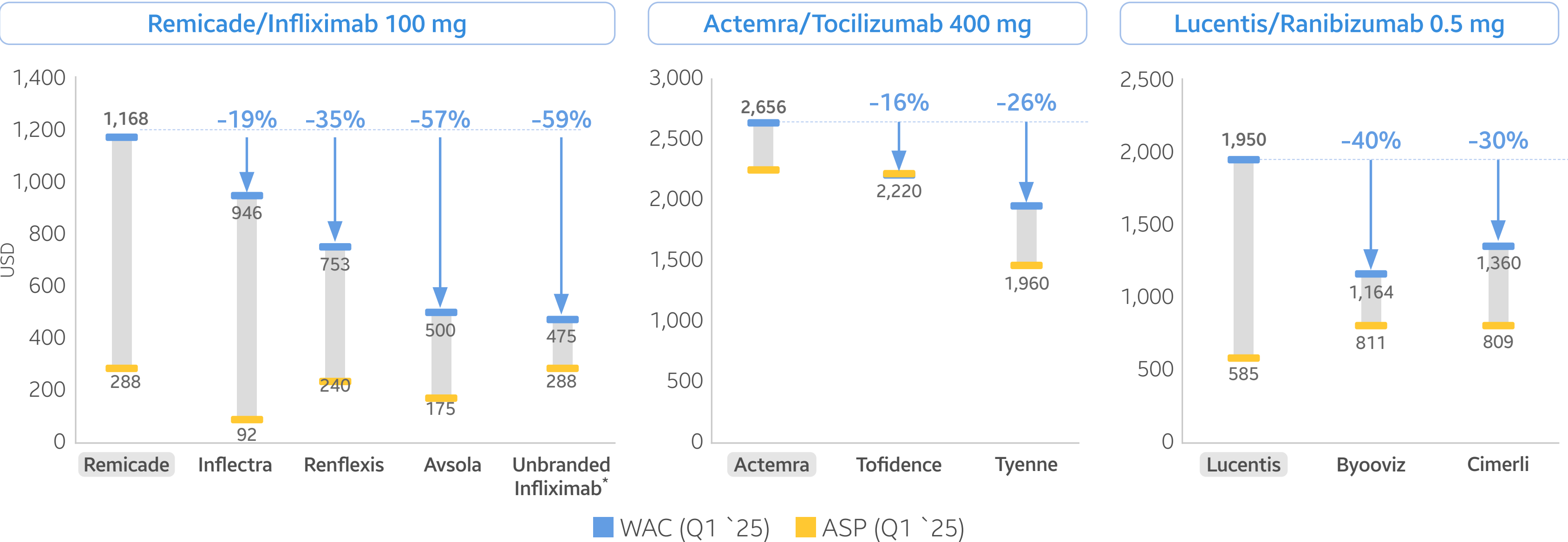
Reference

# Immunology & Ophthalmology

## WAC and ASP – Q1 2025

- ✦ In infliximab, both reference product and biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- ✦ Two tocilizumab biosimilars, Tofidence and Tyenne, newly launched last quarter with -16% and -26% WAC discounts, respectively.
- ✦ With only two competing biosimilars on the market, ranibizumab WACs represent -30% to -40% discounts compared to the reference product.

Figure 5. Q1 2025 WAC and ASP<sup>2,3</sup>



Products are listed in order of launch  
ASP: Average Sales Price; WAC: Wholesale Acquisition Cost  
\*Janssen's Remicade without the brand name

Biosimilar Price – Medical Benefit

- Oncology
- Supportive Care
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Biosimilar Price – Pharmacy Benefit

- Immunology & Endocrinology

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- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
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- Immunology
- Endocrinology
- Ophthalmology

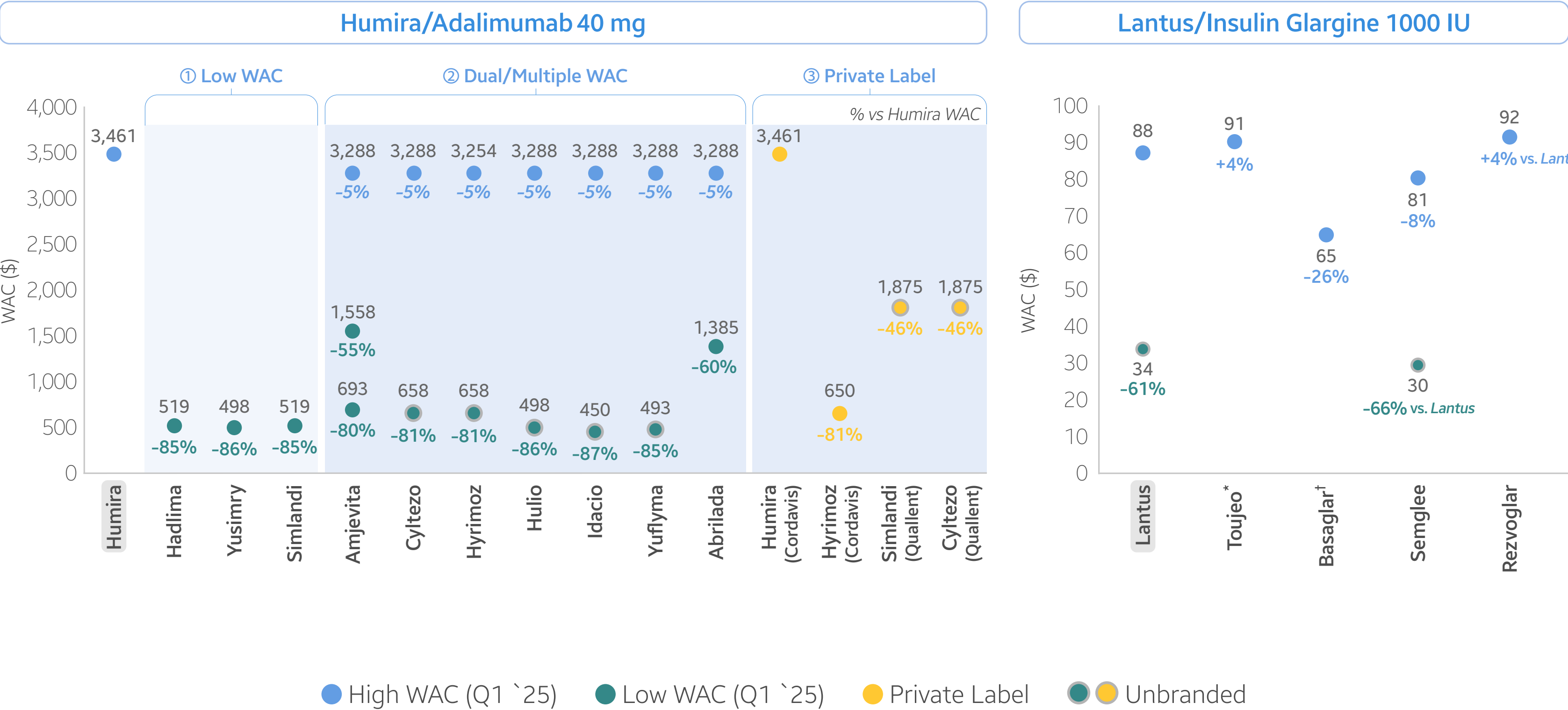
Biosimilar Deep Dive

Reference

# Immunology & Endocrinology WAC – Q1 2025

- ✦ Adalimumab & insulin glargine categories reflect recent pricing practices such as multiple WAC options and unbranded biologics.
- ✦ In the adalimumab market, Private Label brands offer alternative WAC prices.

Figure 6. Q1 2025 WAC<sup>2</sup>



Products are listed in order of launch  
WAC: Wholesale Acquisition Cost  
\*Toujeo is high dose version of Lantus †Basaglar is not a biosimilar, approved under the FDA's New Drug Application pathway



## III. Biosimilar Market Dynamics

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

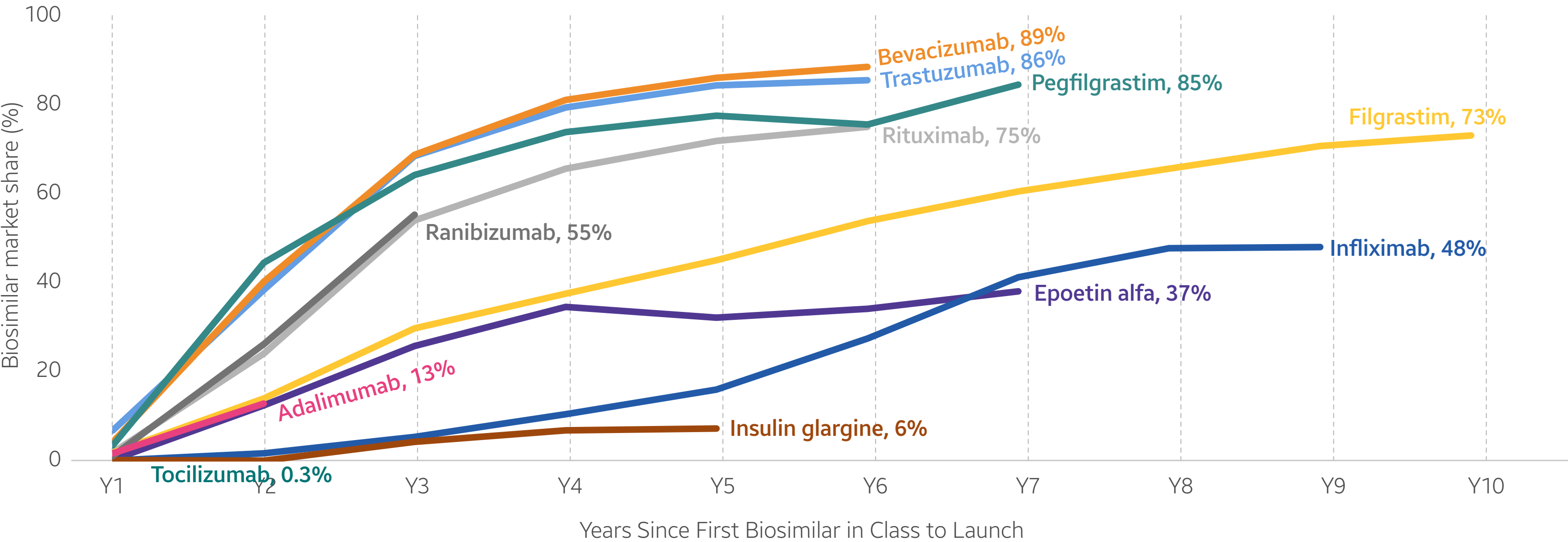
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Biosimilar Volume Uptake Varies by Molecule

★ On average, biosimilars have gained 53% market share within 5 years post initial launch.<sup>†</sup> Each molecule has demonstrated unique biosimilar uptake speeds and can be categorized into fast or slow uptake markets.

- 1) **Fast Uptake Markets:** Oncology<sup>\*</sup>, ophthalmology, and pegfilgrastim biosimilars.  
Five years post launch, average biosimilar market share reached 81%.<sup>†</sup>
- 2) **Slow Uptake Markets:** Immunology<sup>‡</sup>, filgrastim, epoetin alfa, and insulin glargine biosimilars.  
On average, only a 26% biosimilar market share was achieved by Year 5.<sup>†</sup>

Figure 7. Biosimilar Market Share Post-Launch<sup>4§¶</sup>



<sup>\*</sup> Trastuzumab, bevacizumab, and rituximab <sup>†</sup> Averages include products that are 5 years or older <sup>‡</sup> Infiximab and adalimumab <sup>§</sup> Calculated based on calendar year <sup>¶</sup> Latest year data only include 3 quarters (~Q3 2024)

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

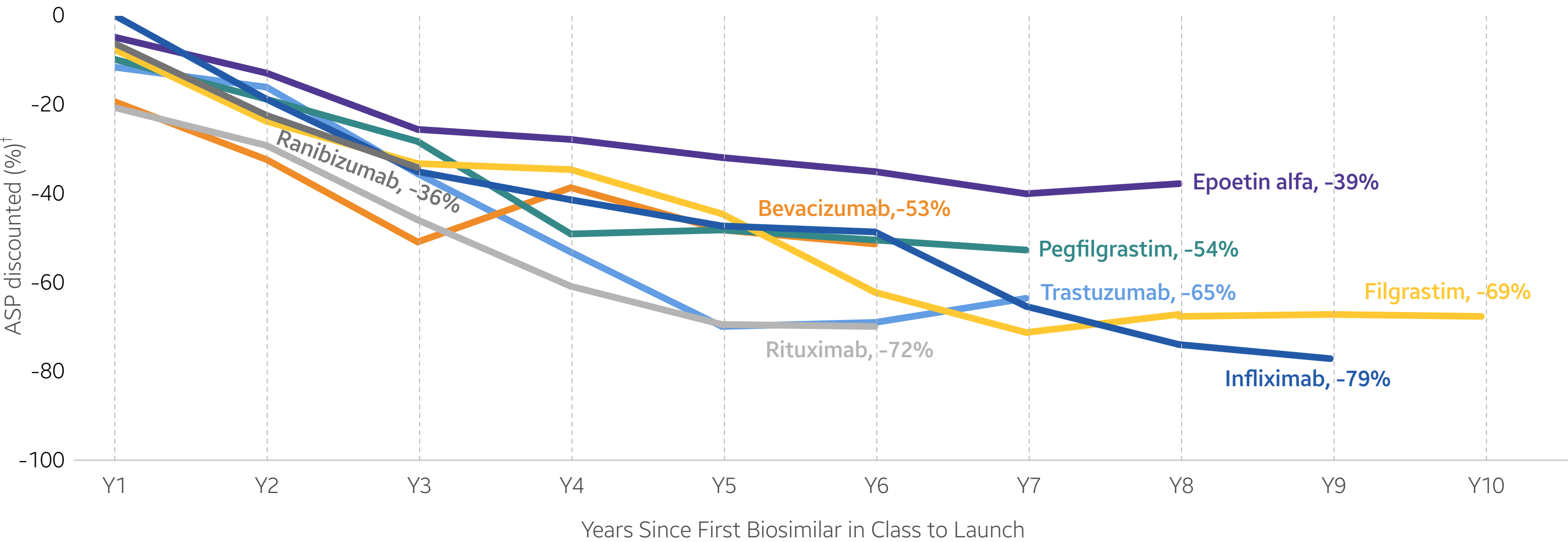
- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Biosimilars are Reducing Drug Costs across Multiple TAs

- ✦ Biosimilar launches have led to significant price decreases over time. On average, ASP declined by 53% 5 years post first biosimilar launch with more mature markets demonstrating increasing price concessions.
- ✦ Recent observed increases in ASP for some markets (e.g. trastuzumab, bevacizumab, pegfilgrastim, and filgrastim) may be due to 1) artifacts of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing and 2) intentional ASP repositioning of some biosimilars.

Figure 8. ASP Trend by Molecule<sup>3</sup>



TA: Therapeutic Area; ASP: Average Sales Price  
† ASP discounted % vs. reference product ASP when first biosimilar in class launch

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
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- Immunology
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- Ophthalmology

# Market Share and ASP Trends - Herceptin (Trastuzumab)

- ✦ As of Q3 2024, the biosimilar share of the trastuzumab market was 86% (Unchanged vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$1,468 (+7% vs. last quarter).
- ✦ Over the last few quarters, many trastuzumab biosimilars have shown ASP increases in a highly competitive market.

Figure 9. Trastuzumab Volume Market Share<sup>4</sup>

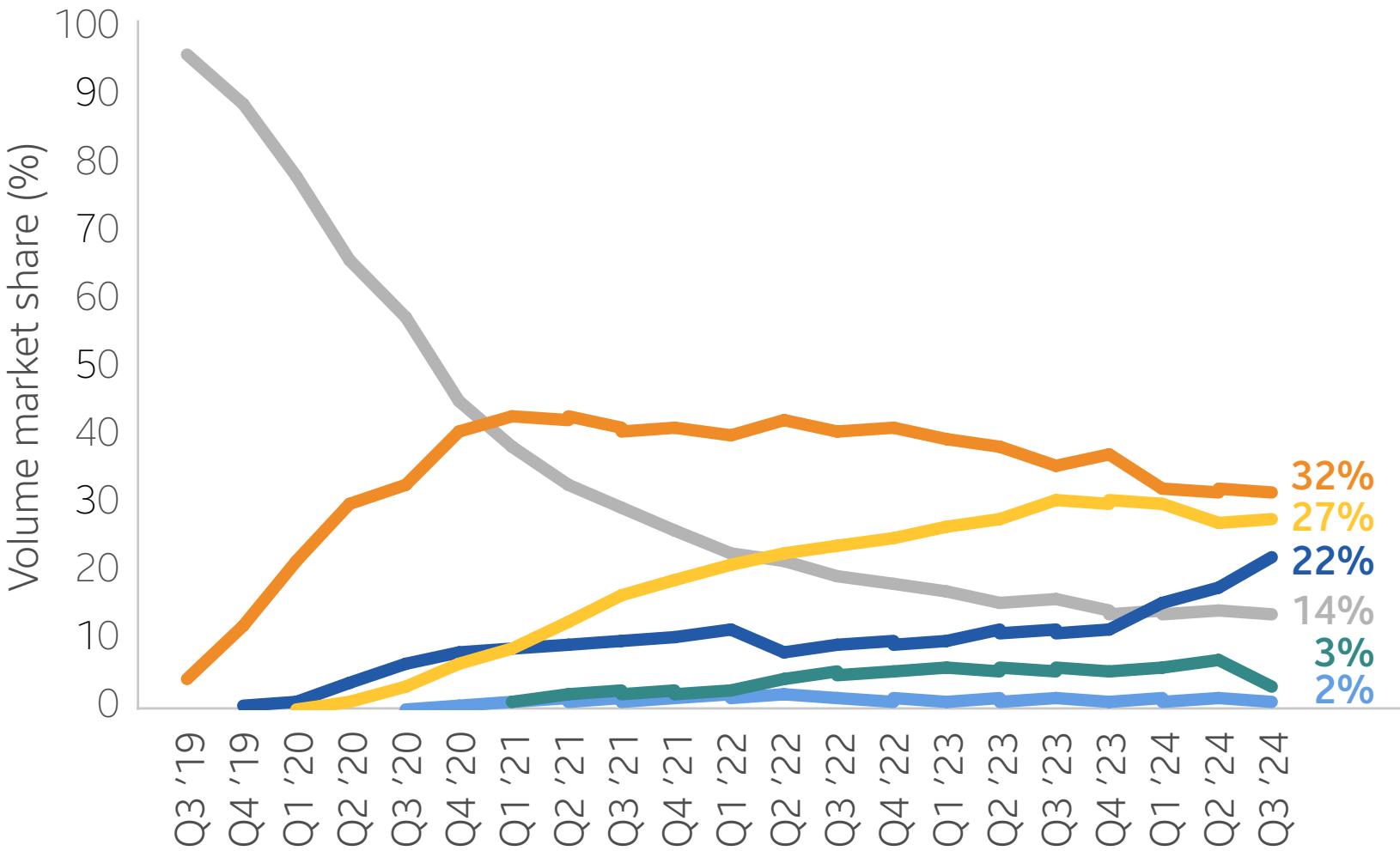
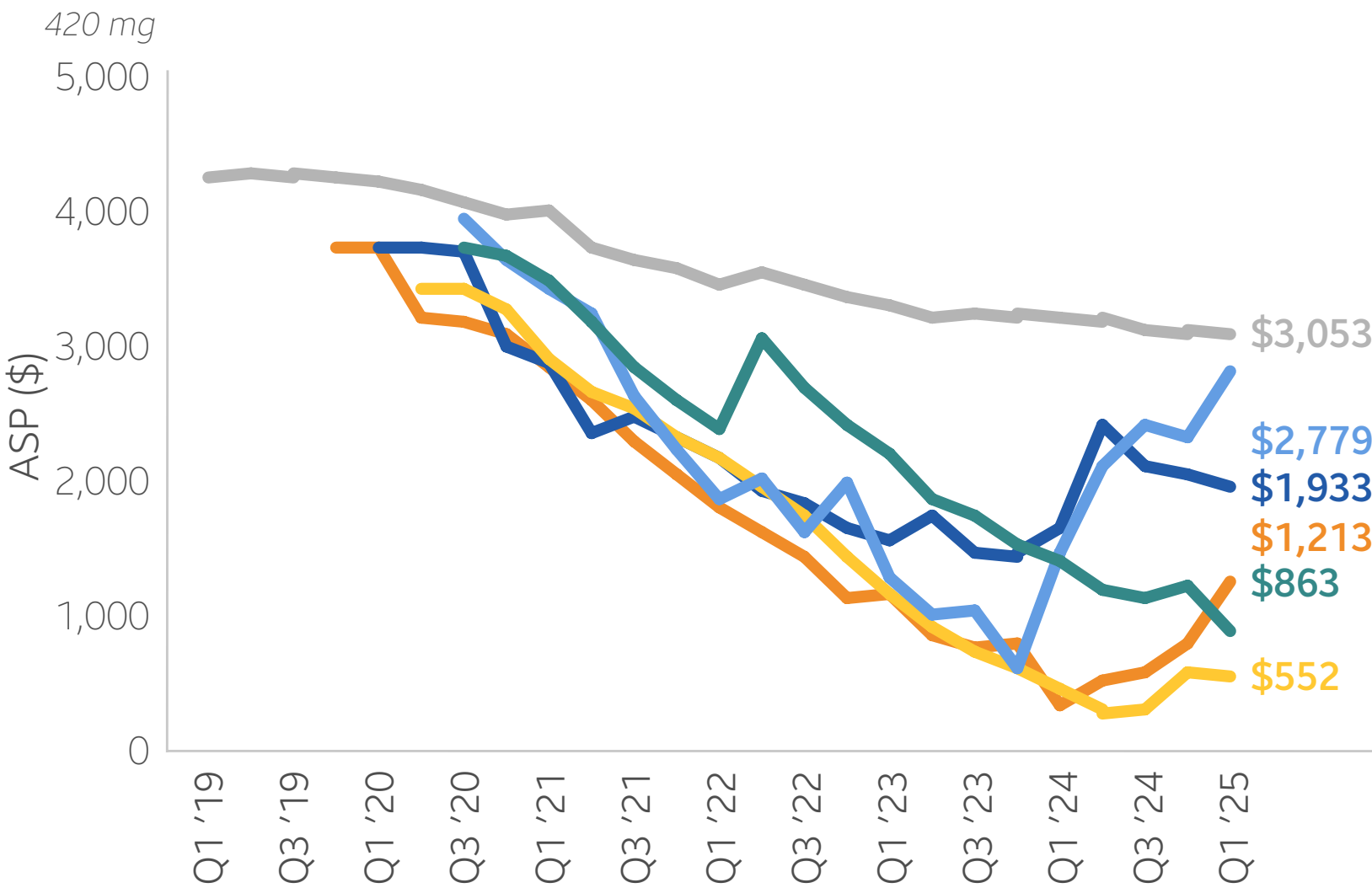


Figure 10. Trastuzumab ASP Trend<sup>3</sup>



Herceptin Kanjinti Ogivri Trazimera Herzuma Ontruzant

Products are listed in legends in order of launch  
ASP: Average Sales Price

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends

## - Avastin (Bevacizumab)

- ✦ As of Q3 2024, the biosimilar share of the bevacizumab market has reached 90% (+1% vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$1,399 (-1% vs. last quarter).
- ✦ Earlier-to-market bevacizumab biosimilars with lower established ASPs (i.e. Mvasi and Zirabev) continue to make up for the majority of market share (81%). However, the market share for the recent biosimilar entrants (i.e. Almsys and Vegzelma) continues to grow.

Figure 11. Bevacizumab Volume Market Share<sup>4</sup>

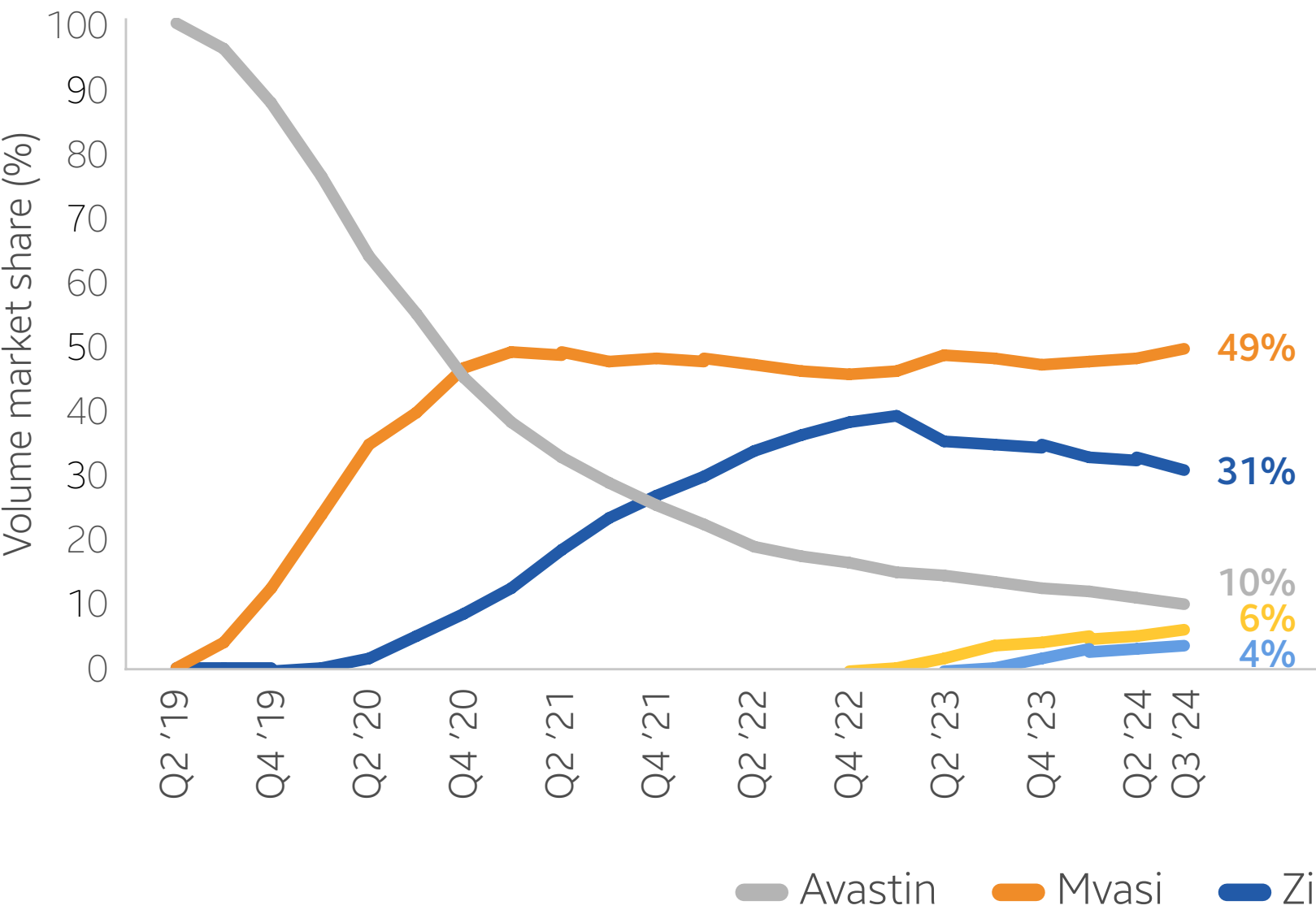
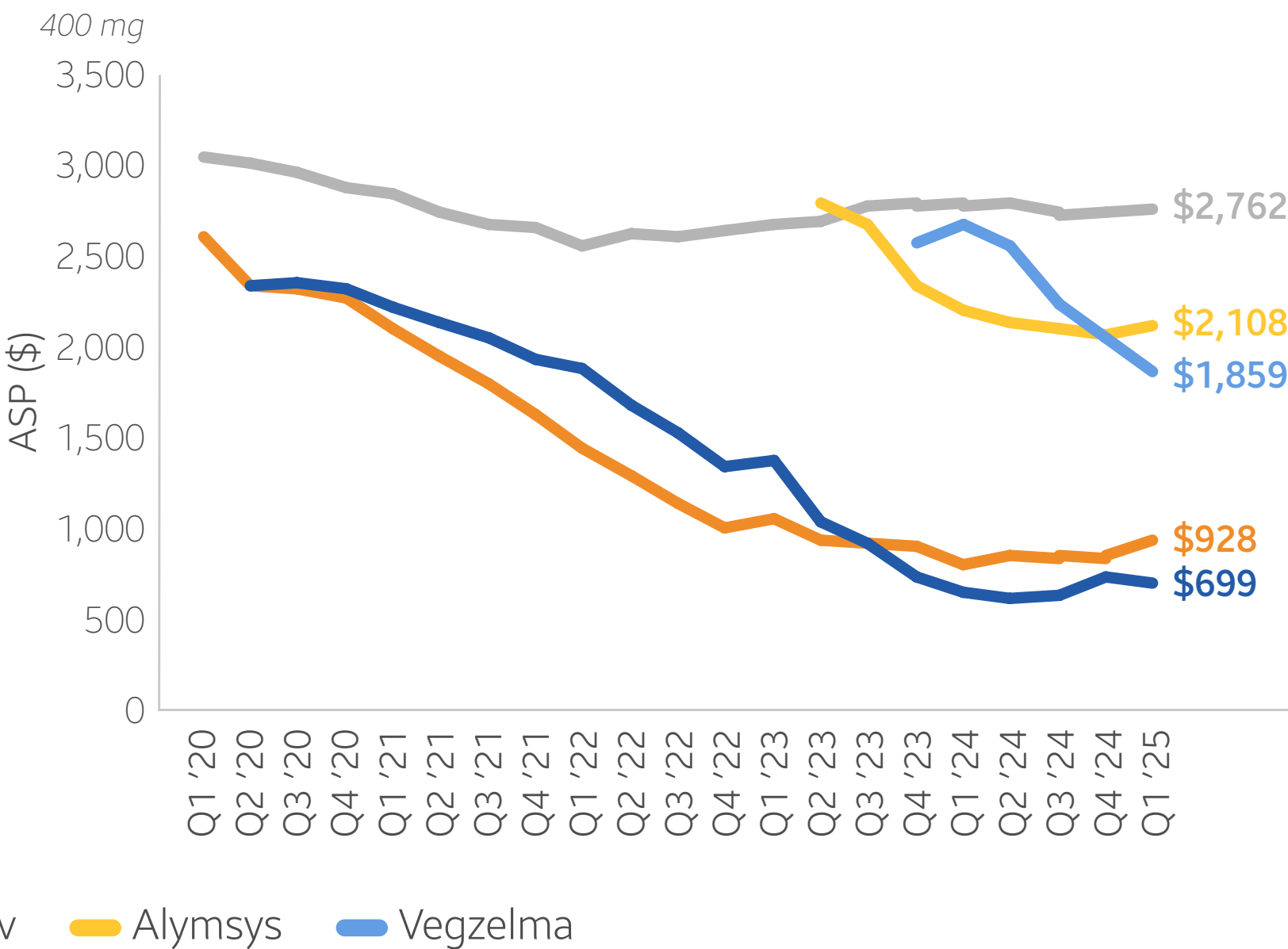


Figure 12. Bevacizumab ASP Trend<sup>3</sup>



Products are listed in legends in order of launch  
ASP: Average Sales Price

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Rituxan (Rituximab)

- ✦ As of Q3 2024, the biosimilar share of the rituximab market was 76% (Unchanged vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$1,247 (-3% vs. last quarter).
- ✦ In the rituximab market, lower priced biosimilars are dominating the market. The later entrant, Riabni, continues to grow in market share as its ASP declines.

Figure 13. Rituximab Volume Market Share<sup>4</sup>

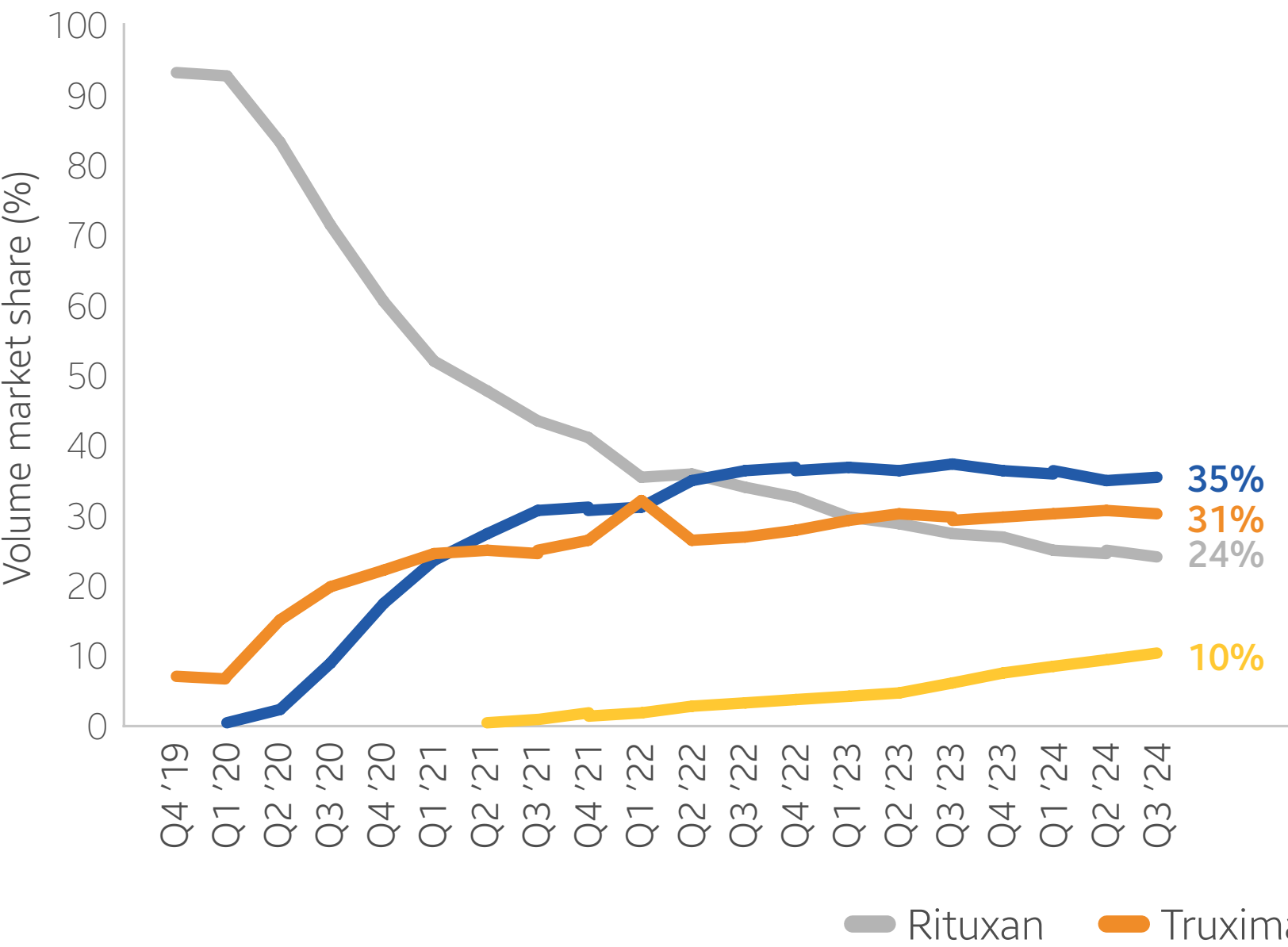
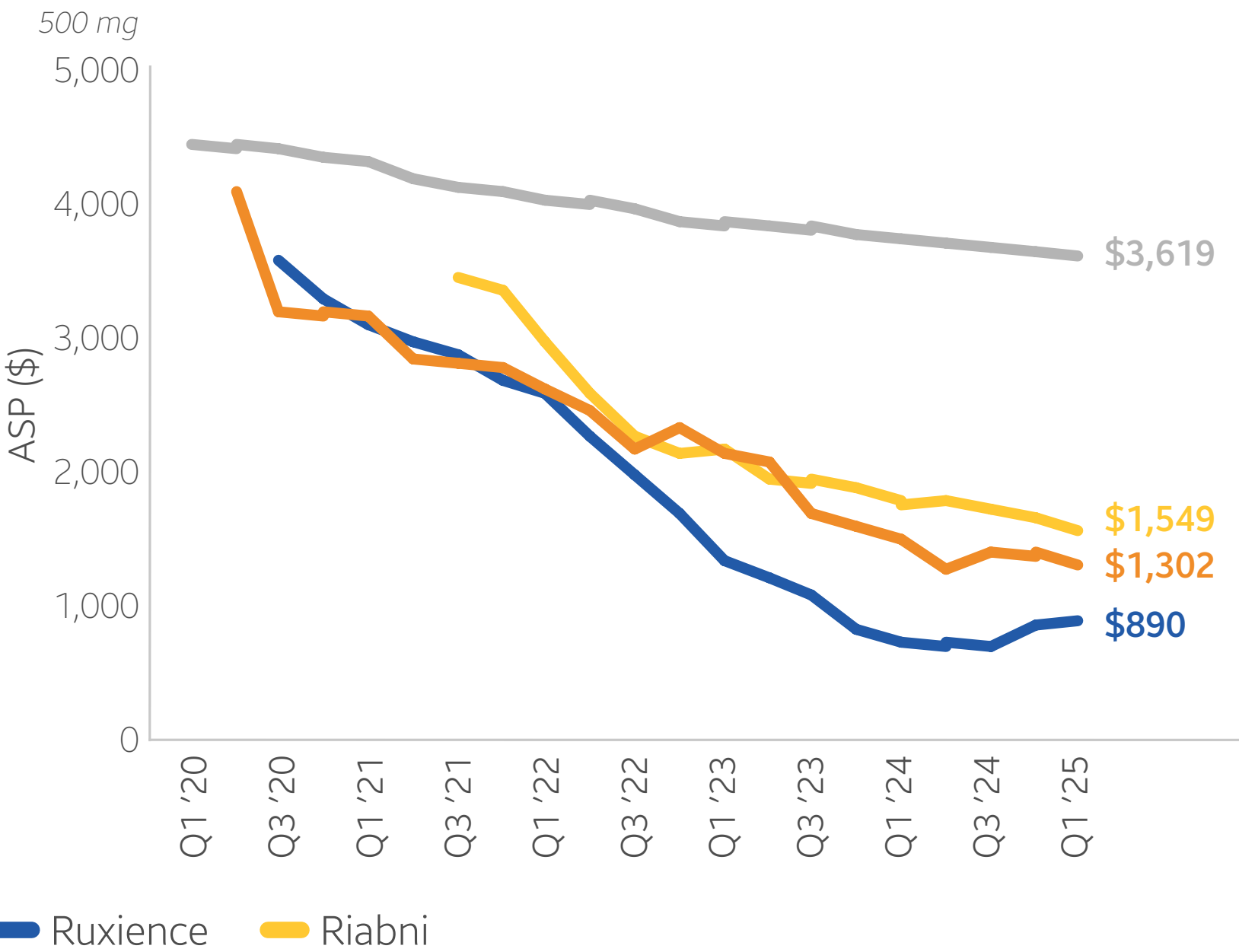


Figure 14. Rituximab ASP Trend<sup>3</sup>



Products are listed in legends in order of launch  
ASP: Average Sales Price

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Neupogen (Filgrastim)

- ✦ As of Q3 2024, the biosimilar share of the filgrastim market was 87% (Unchanged vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$140 (-1% vs. last quarter).
- ✦ In the filgrastim market, the market leader, Zarxio, has recently shown ASP price increases while newer entrants Nivestym and Releuko gain in market share.

Figure 15. Filgrastim Volume Market Share<sup>4</sup>

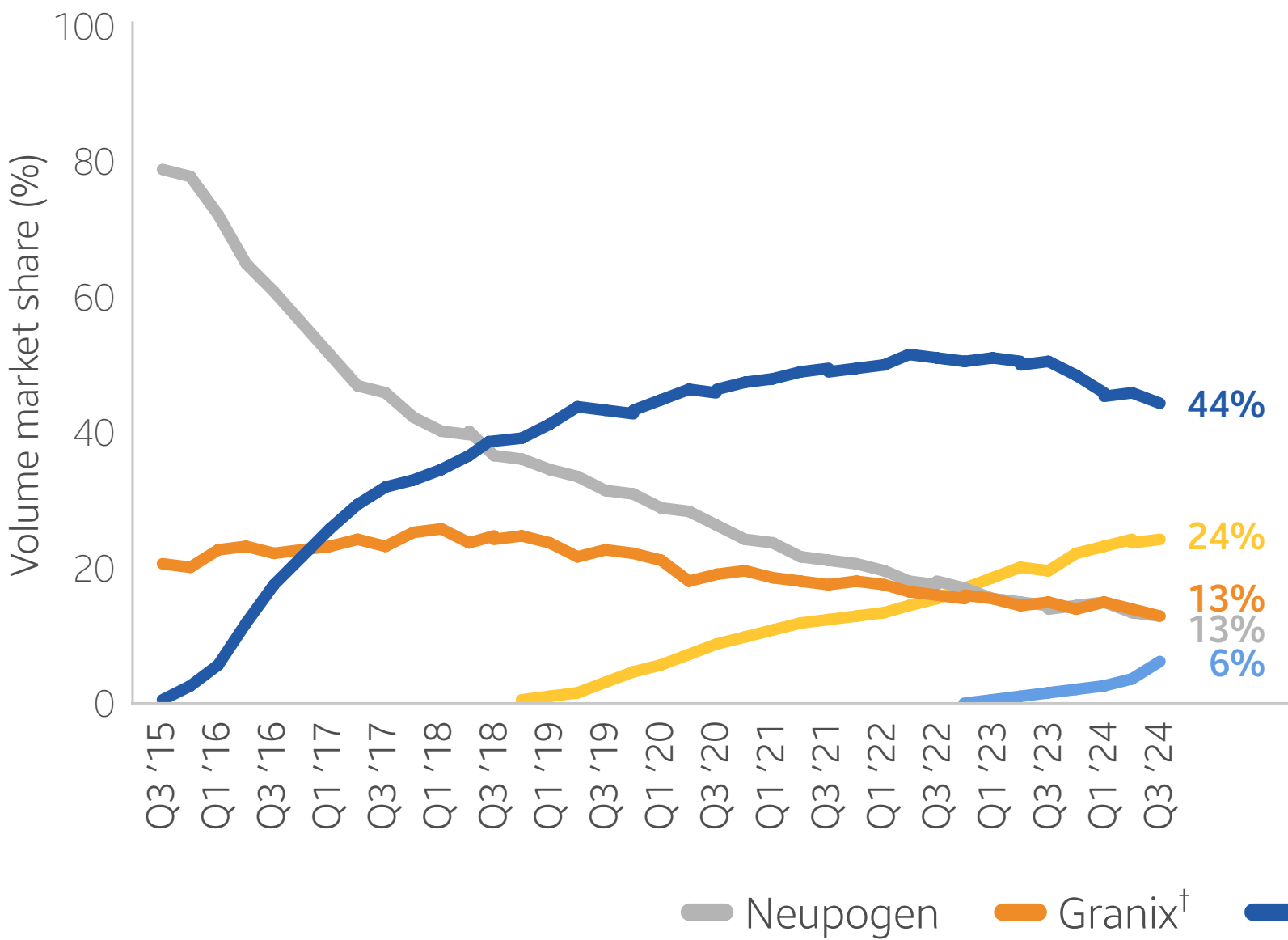
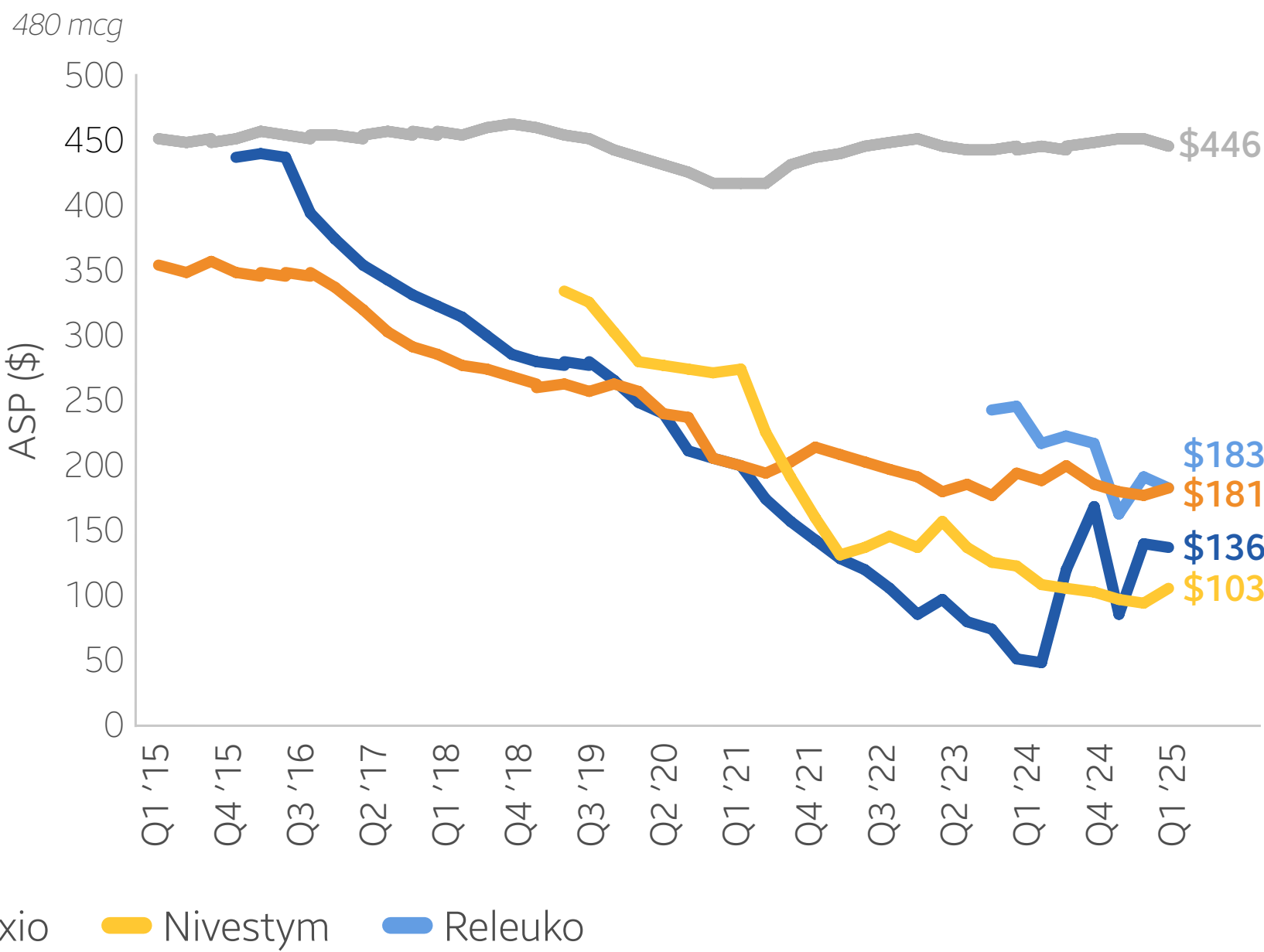


Figure 16. Filgrastim ASP Trend<sup>3</sup>



Legends are listed in order of launch  
ASP: Average Sales Price  
† Granix is not abiosimilar; It's approved under FDA, a new drug application pathway

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- ✦ As of Q3 2024, the biosimilar share of the pegfilgrastim market was 85% (Unchanged vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$2,050 (-0.5% vs. last quarter).
- ✦ In the pegfilgrastim market, despite the originator pursuing competitive price discounts, Udenyca and Fulphila with more stable ASPs remain the market leaders.

Figure 17. Pegfilgrastim Volume Market Share<sup>4</sup>

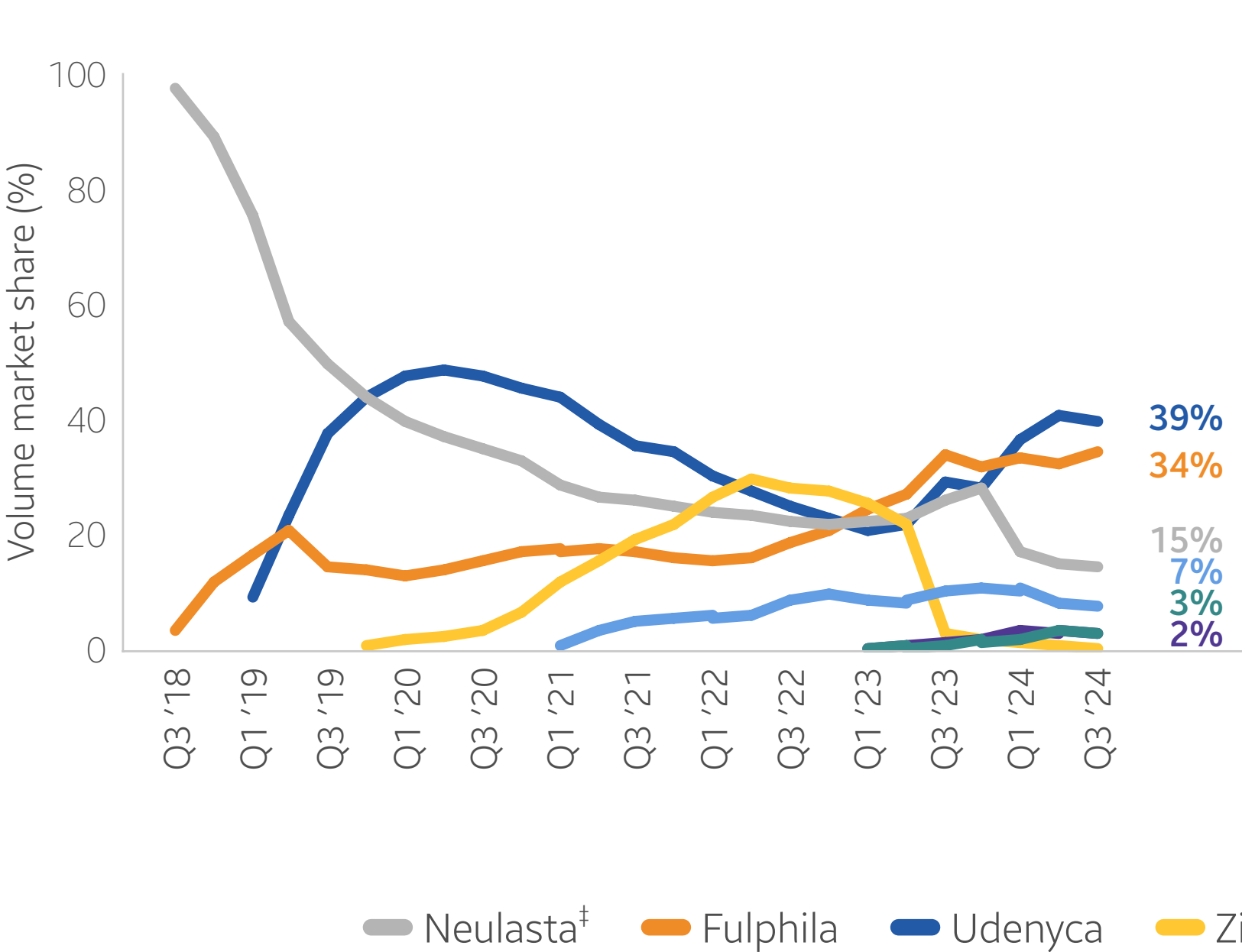
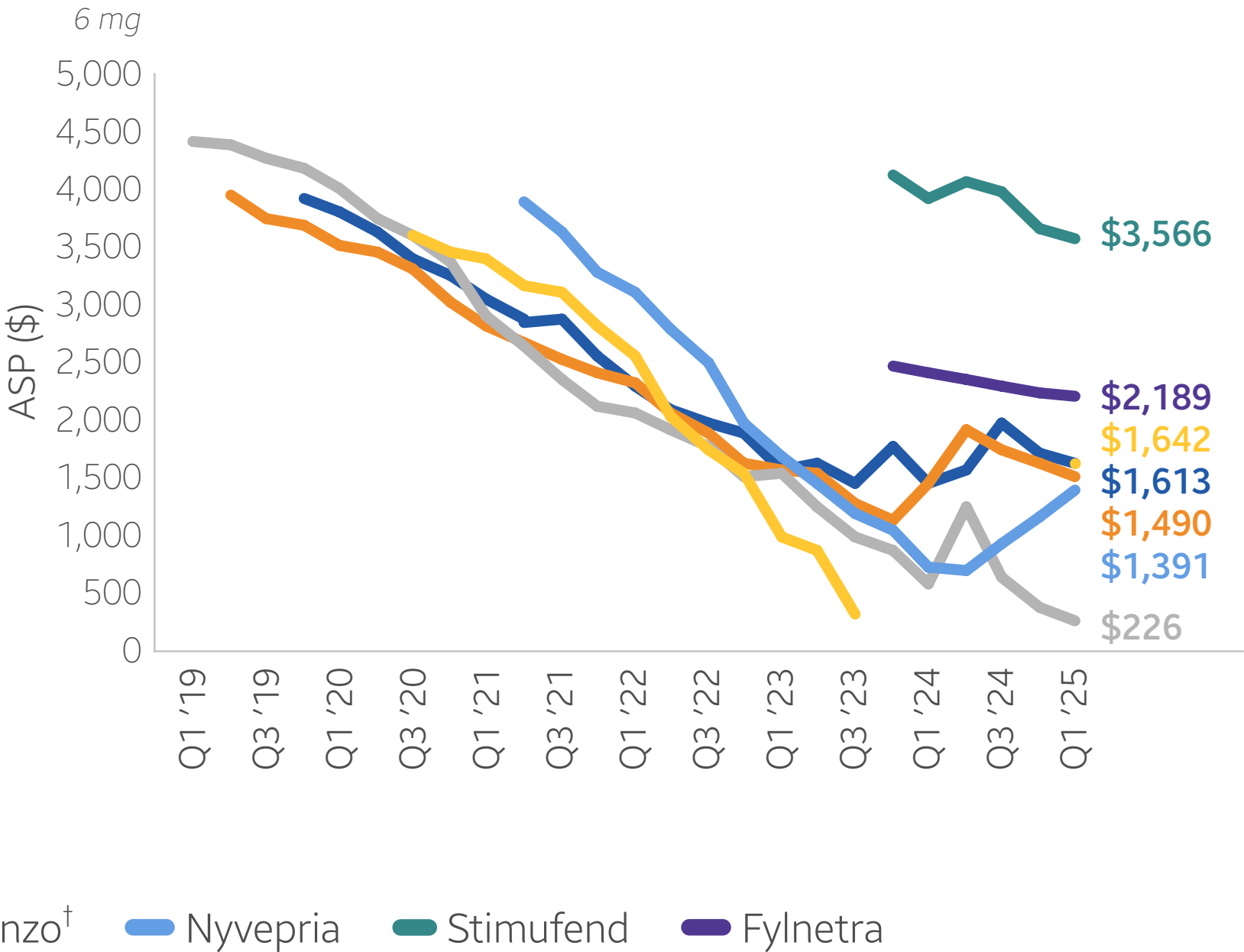


Figure 18. Pegfilgrastim ASP Trend<sup>3</sup>



Legends are listed in order of launch ASP: Average Sales Price  
<sup>†</sup>Ziextenzo ZiextenzoASP republished in Q1 2025 <sup>†</sup>Onpro is not included

- Oncology
- Supportive Care
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- Ophthalmology

# Market Share and ASP Trends

## - Epogen/Procrit (Epoetin alfa)

- ✦ Retacrit, the only biosimilar of epoetin alfa, maintains over a third of the epoetin alfa market share.
- ✦ By matching ASP, the two reference products are maintaining maintained a combined share of approximately 60-70%.

Figure19. Epoetin Alfa Volume Market Share<sup>4</sup>

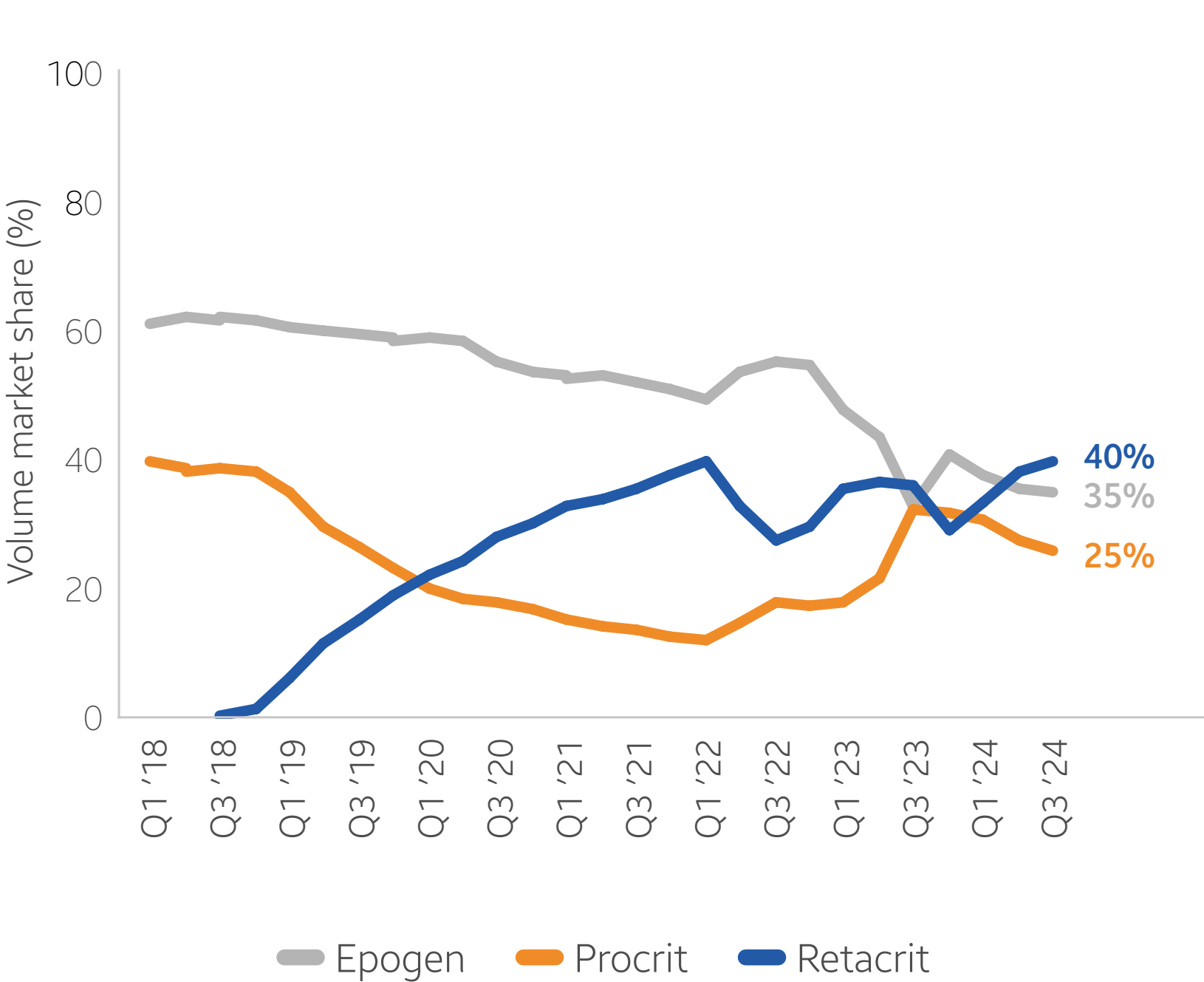
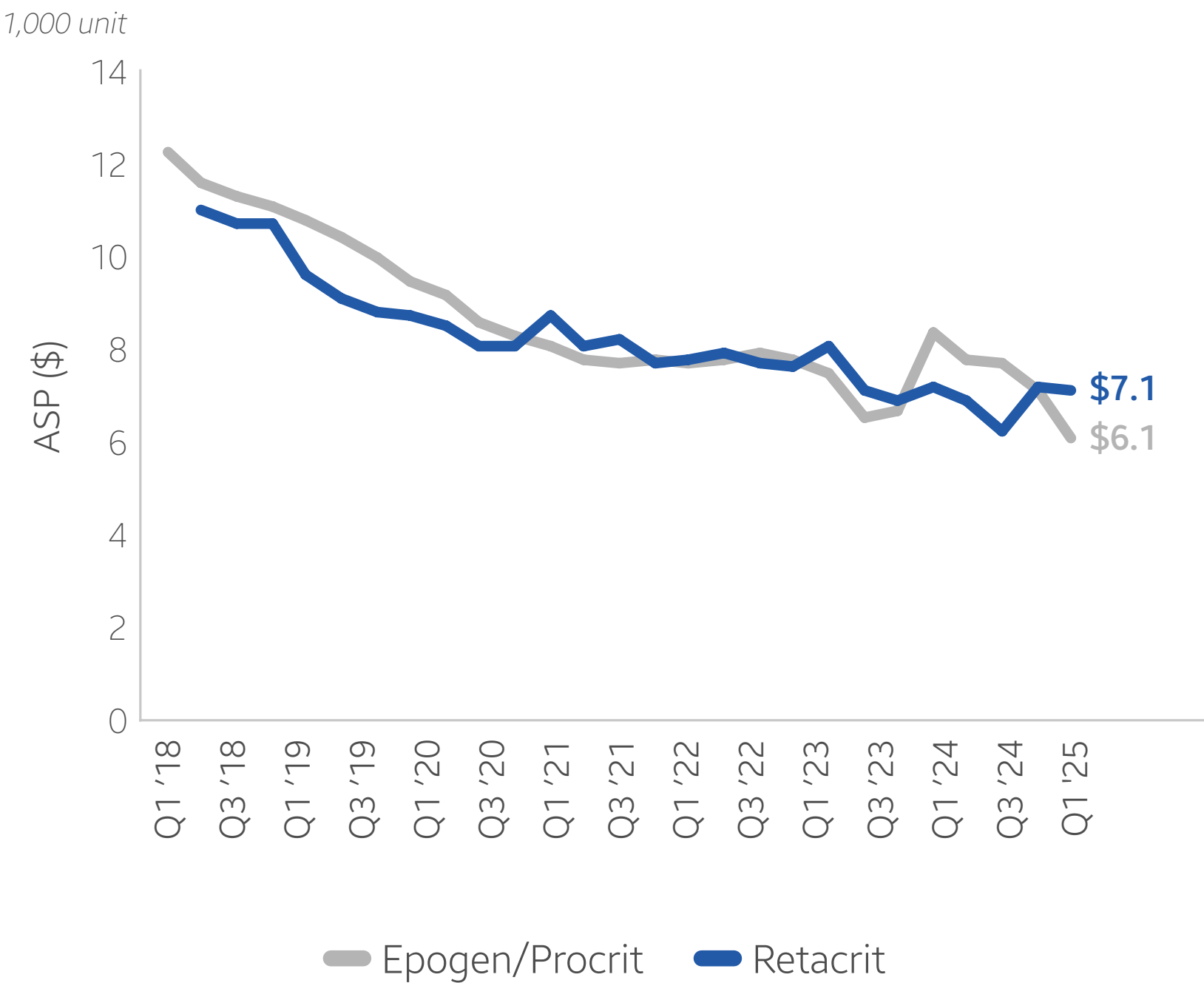


Figure 20. Epoetin alfa ASP Trend<sup>3</sup>



Legends are listed in order of launch  
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- Oncology
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# Market Share and ASP Trends

## - Remicade (Infliximab)

- ✦ As of Q3 2024, Infliximab biosimilar market share has reached 48% (+1% vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$169 (-7% vs. last quarter).
- ✦ Janssen’s competitive ASP pricing and launch of unbranded infliximab of Remicade in Q4 2021 have allowed the reference product to hold onto the market leading position.

Figure 21. Infliximab Volume Market Share<sup>4</sup>

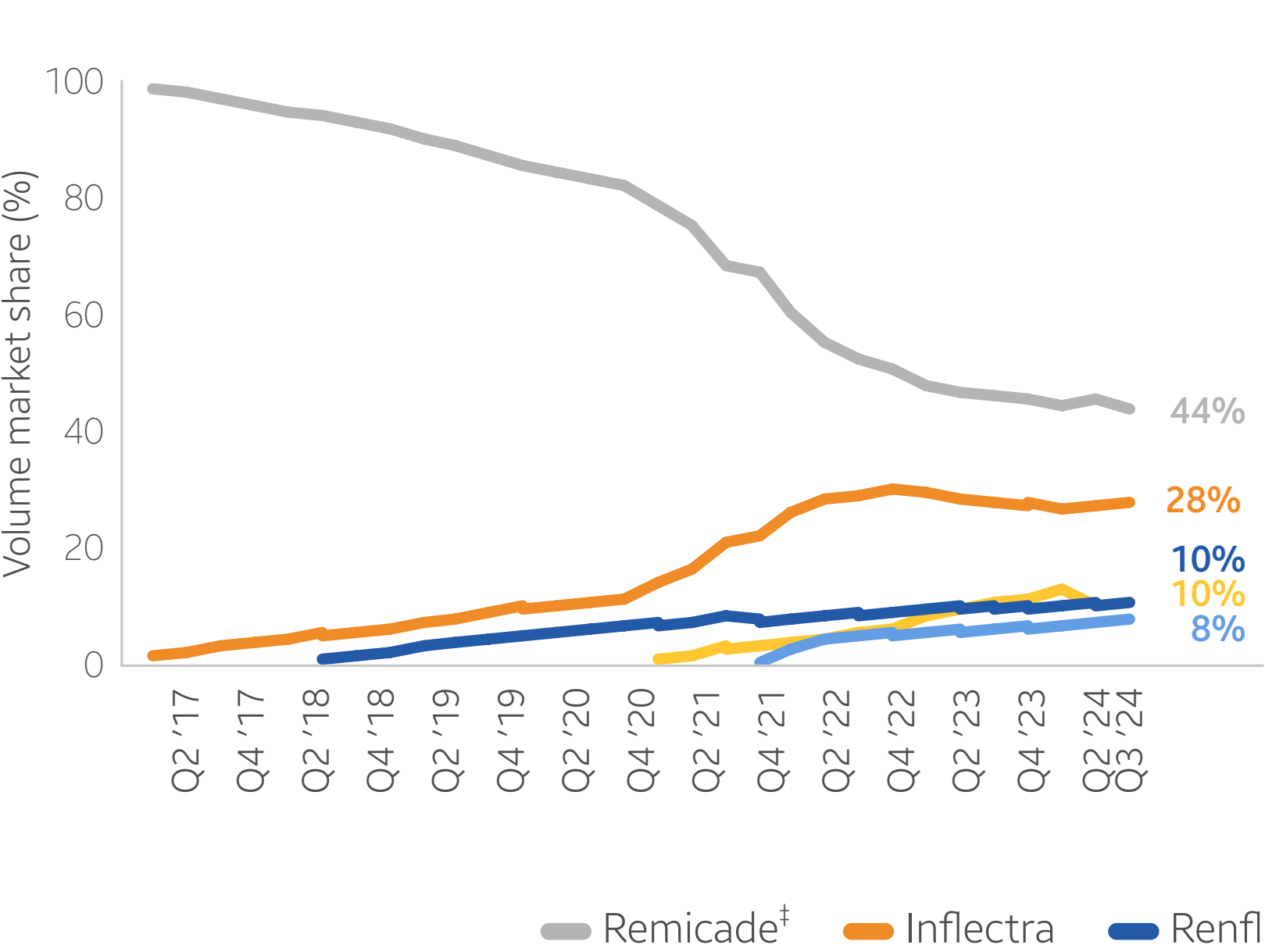
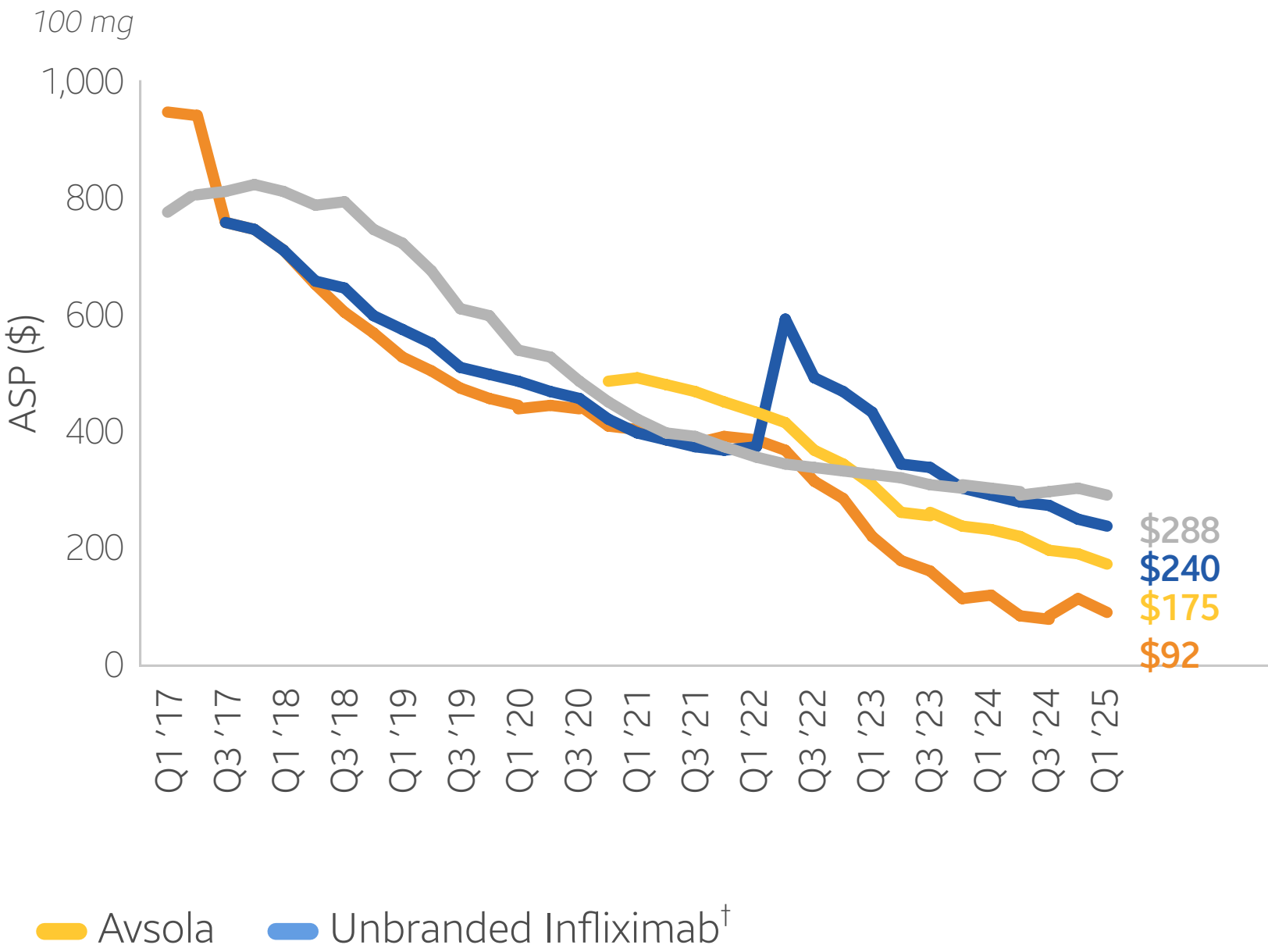


Figure 22. Infliximab ASP Trend<sup>3</sup>



Legends are listed in order of launch  
ASP: Average Sales Price  
<sup>†</sup>Janssen’s Remicade without the brand name <sup>‡</sup>Remicade and Unbranded Infliximab share a J code

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
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- Ophthalmology

# Market Share and WAC Trends - Humira (Adalimumab)

- ✦ As of Nov 2024, adalimumab biosimilar market share has reached 23% (+1% vs. Aug 24).
  - Most biosimilar gains have come from Hyrimoz and Hadlima.
- ✦ Biosimilar brands provide the market with diverse WAC pricing options.
  - 1) Hadlima, Yusimry, and Simlandi offer a low WAC: ~85-86% less than Humira.
  - 2) Cyltezo, Amjevita, Hyrimoz, Hulio, Idacio, Yuflyma, and Abrilada offer dual/multiple pricing options (i.e. high and low WAC).
  - 3) Quallent's private label strategy reflects an increase in WAC price for Simlandi and Cyltezo, whereas Cordavis's strategy offers Hyrimoz at low WAC pricing consistent with the non-private label product.

Figure 23. Adalimumab Volume Market Share<sup>5</sup>

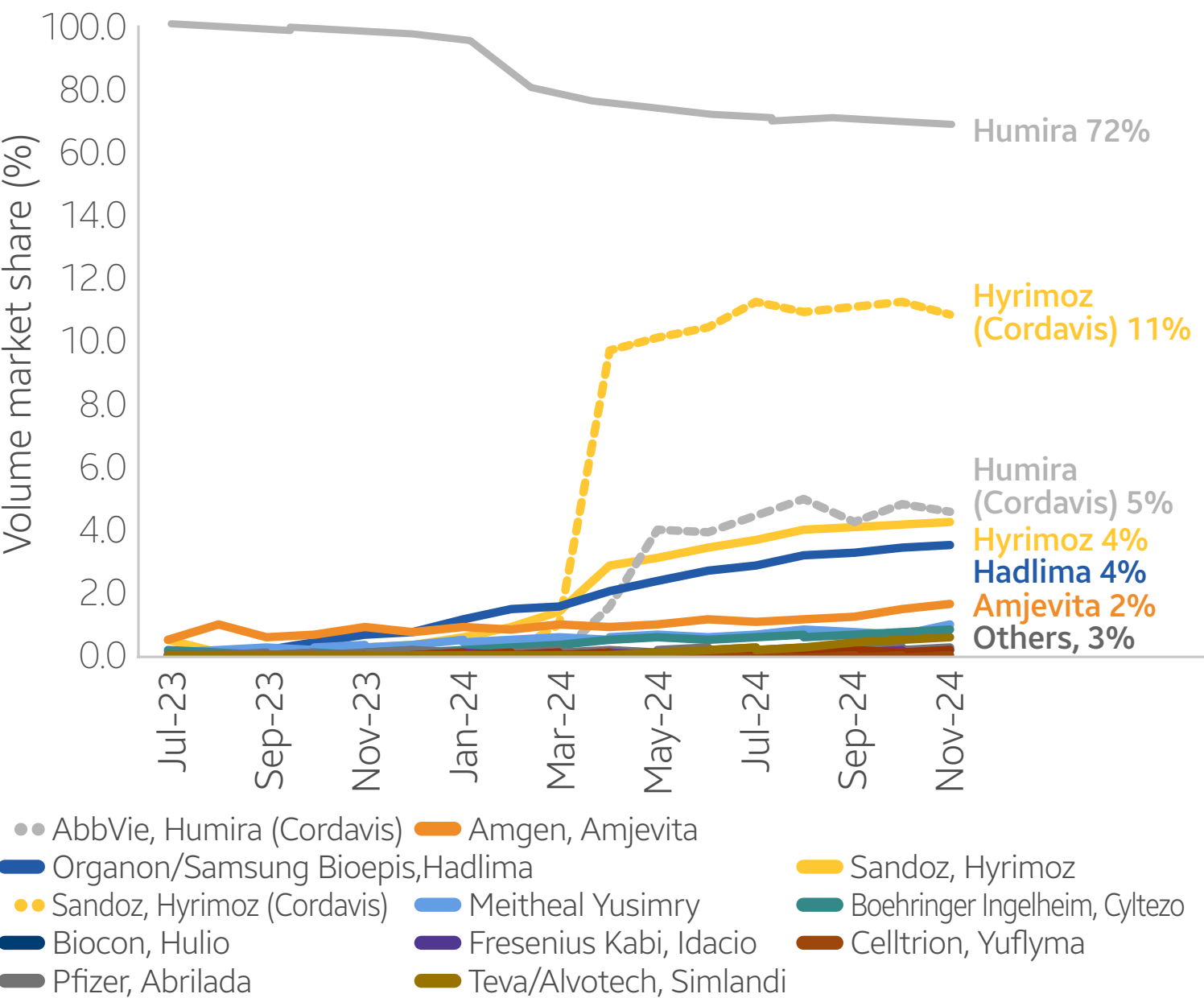
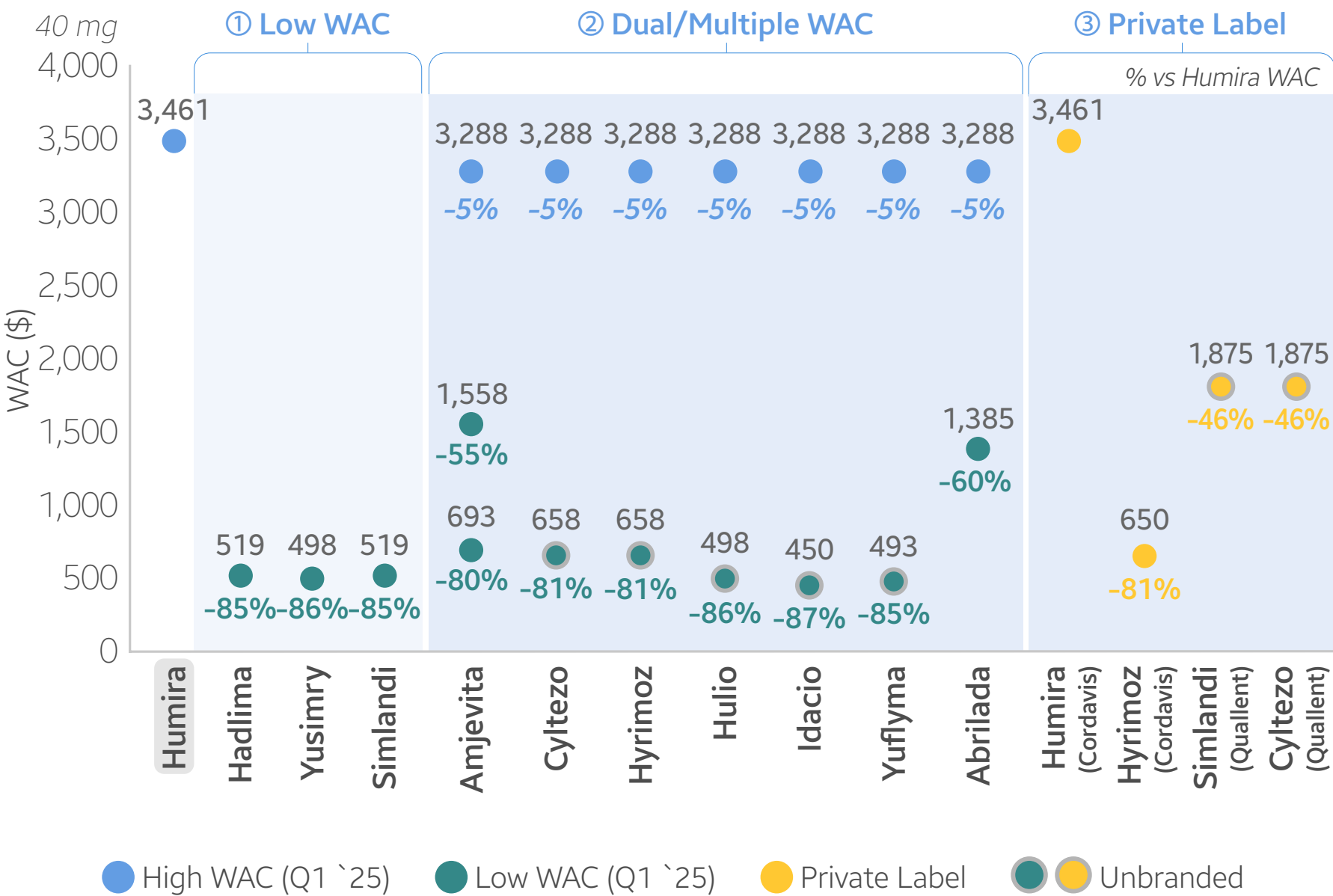


Figure 24. Adalimumab WAC Trend<sup>2</sup>



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- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
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- Ophthalmology

# Market Share and ASP Trends

## - Actemra (Tocilizumab)

- ✦ As of Q3 2024, the penetration of tocilizumab biosimilars is not significant as they have only been in the market for a few months.
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$1,840.
- ✦ Although the tocilizumab biosimilar market is still emerging, Tyenne offers an ASP discount of 35% versus the originator and is growing modestly when compared to Tofidence.

Figure 25. Tocilizumab Volume Market Share<sup>4</sup>

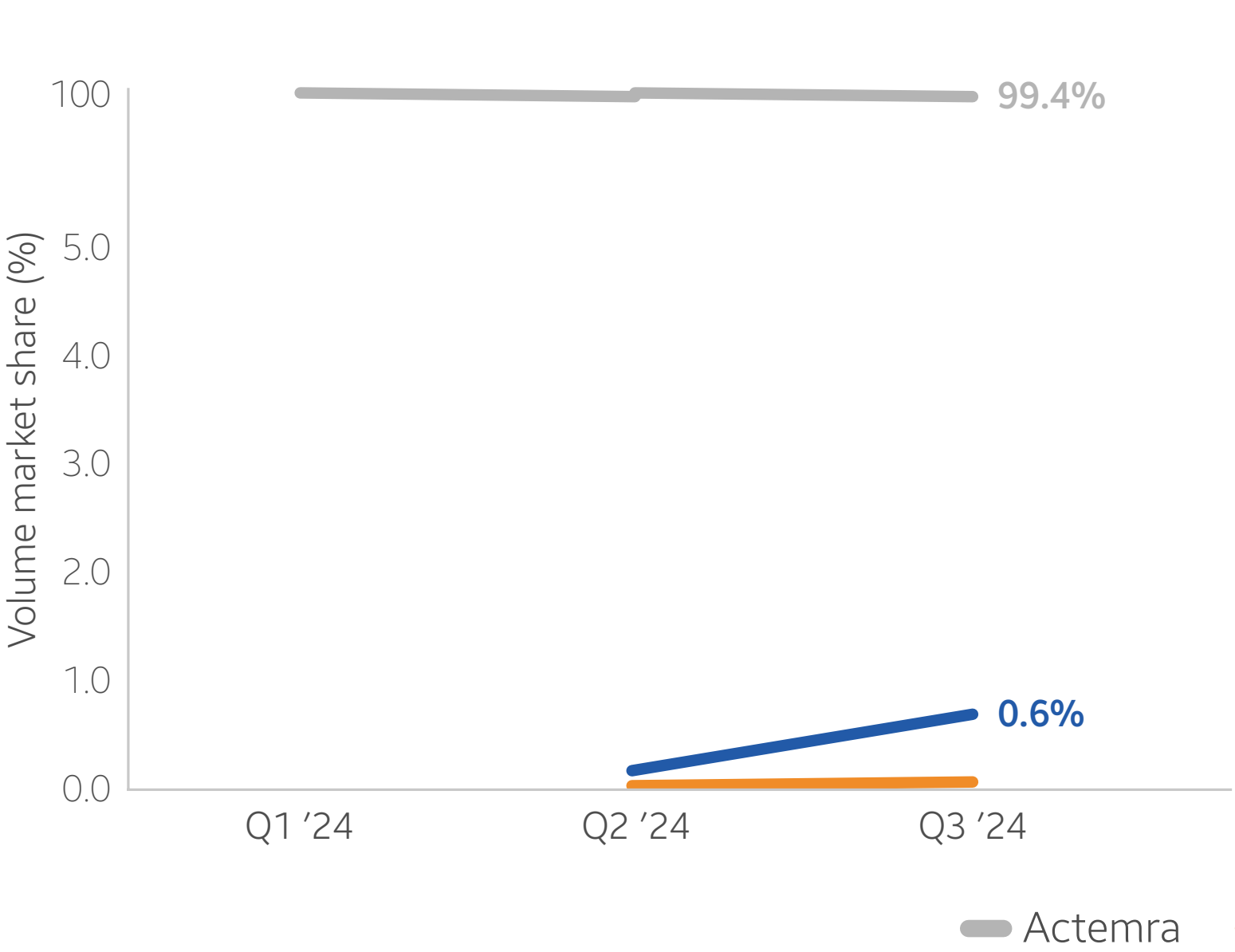


Figure 26. Tocilizumab ASP Trend<sup>3</sup>



ASP: Average Sales Price  
\*The WAC price of Actemra Subcutaneous Solution Prefilled Syringe 162 MG/0.9 ML and Subcutaneous Solution Auto-injector 162 MG/0.9 ML

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- Immunology & Endocrinology

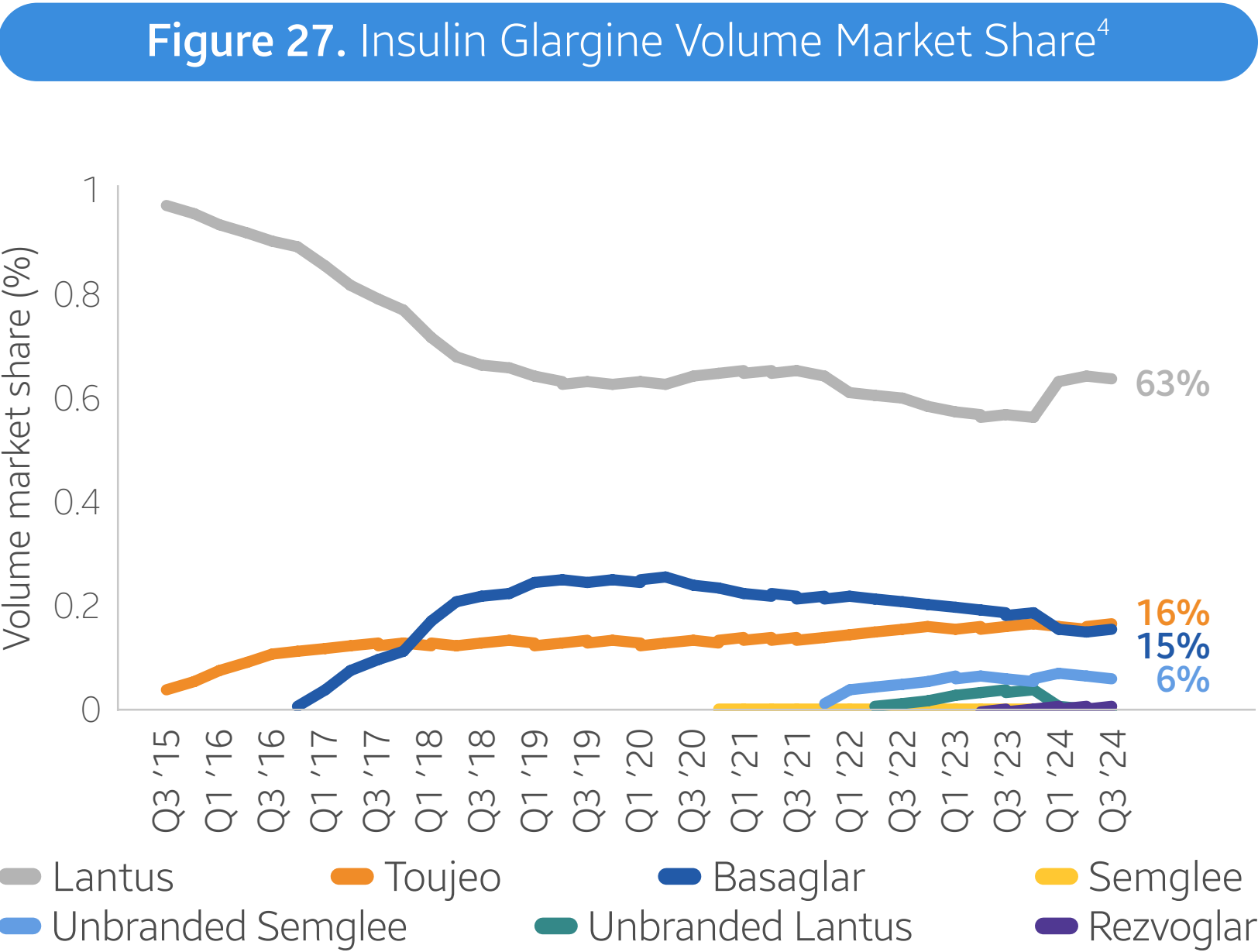
- Biosimilar Market Adoption & Price Erosion

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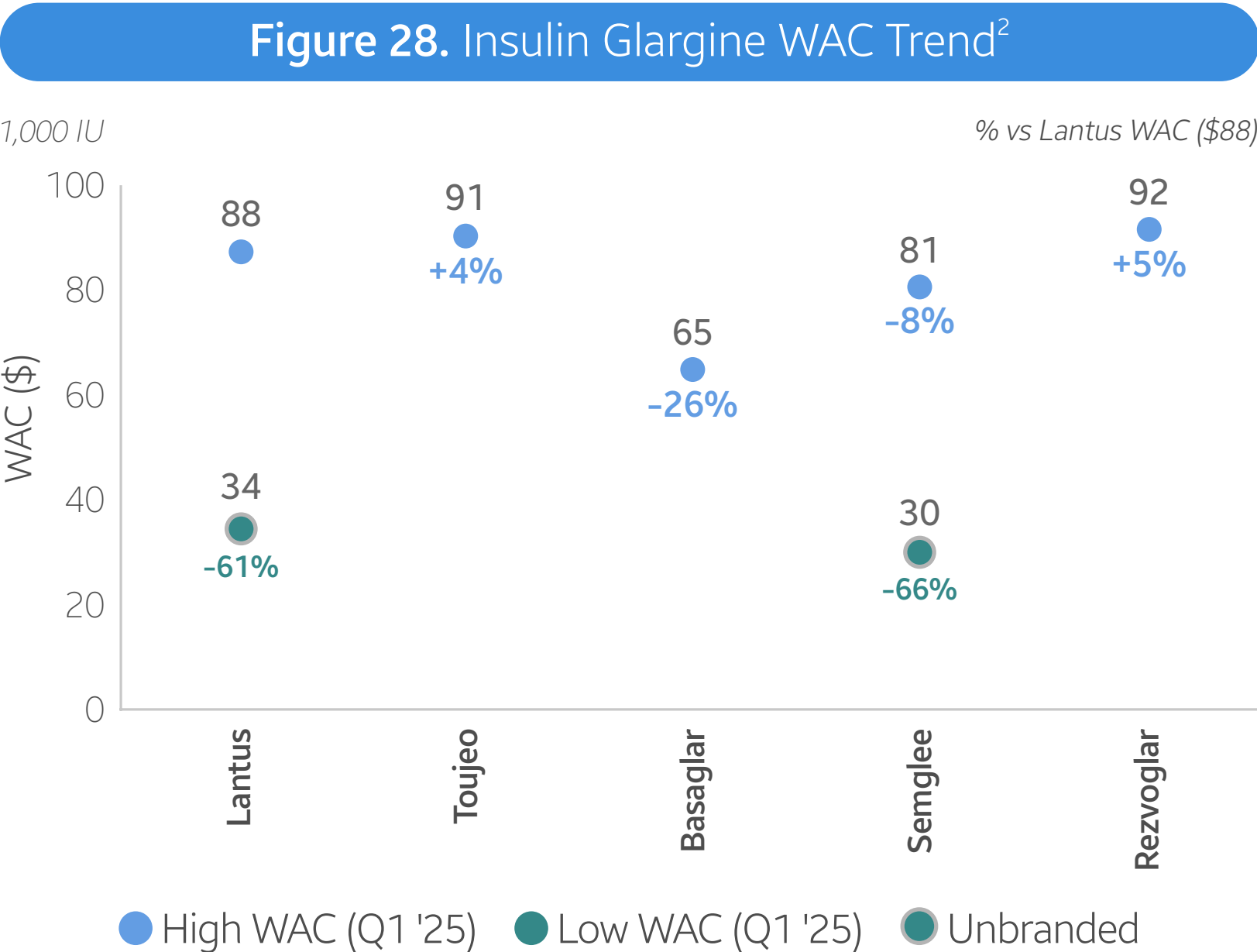
# Market Share and WAC Trends

## - Lantus (Insulin glargine)

- ✦ As of Q3 2024, insulin glargine biosimilar\* market share is 6% (Unchange vs. last quarter)
- ✦ Sanofi's dual pricing strategy and competitive rates have helped maintaining Lantus' position as the market leader
- ✦ *Insulin Glargine Market Background*
  - Lantus (Sanofi): reference product, available unbranded
  - Toujeo (Sanofi): higher dose insulin glargine product
  - Rezvoglar (Eli Lilly): Lantus biosimilar, interchangeable
  - Semglee (Biocon): Lantus biosimilar, available unbranded
  - Basaglar (Eli Lilly): ISG product approved via New Drug Application pathway



Legends are listed in order of launch  
ISG: Insulin glargine; WAC: Wholesale Acquisition Cost  
\*Semglee, Unbranded Semglee and Rezvola



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- Immunology & Endocrinology

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# Market Share and ASP Trends

## - Lucentis (Ranibizumab)

- ✦ As of Q3 2024, ranibizumab biosimilar market share has reached 57% (+1% vs. last quarter).
- ✦ As of Q1 2025, the average ASP of all biosimilar products is \$810 (-9% vs. last quarter).

Figure 29. Ranibizumab Volume Market Share<sup>4</sup>

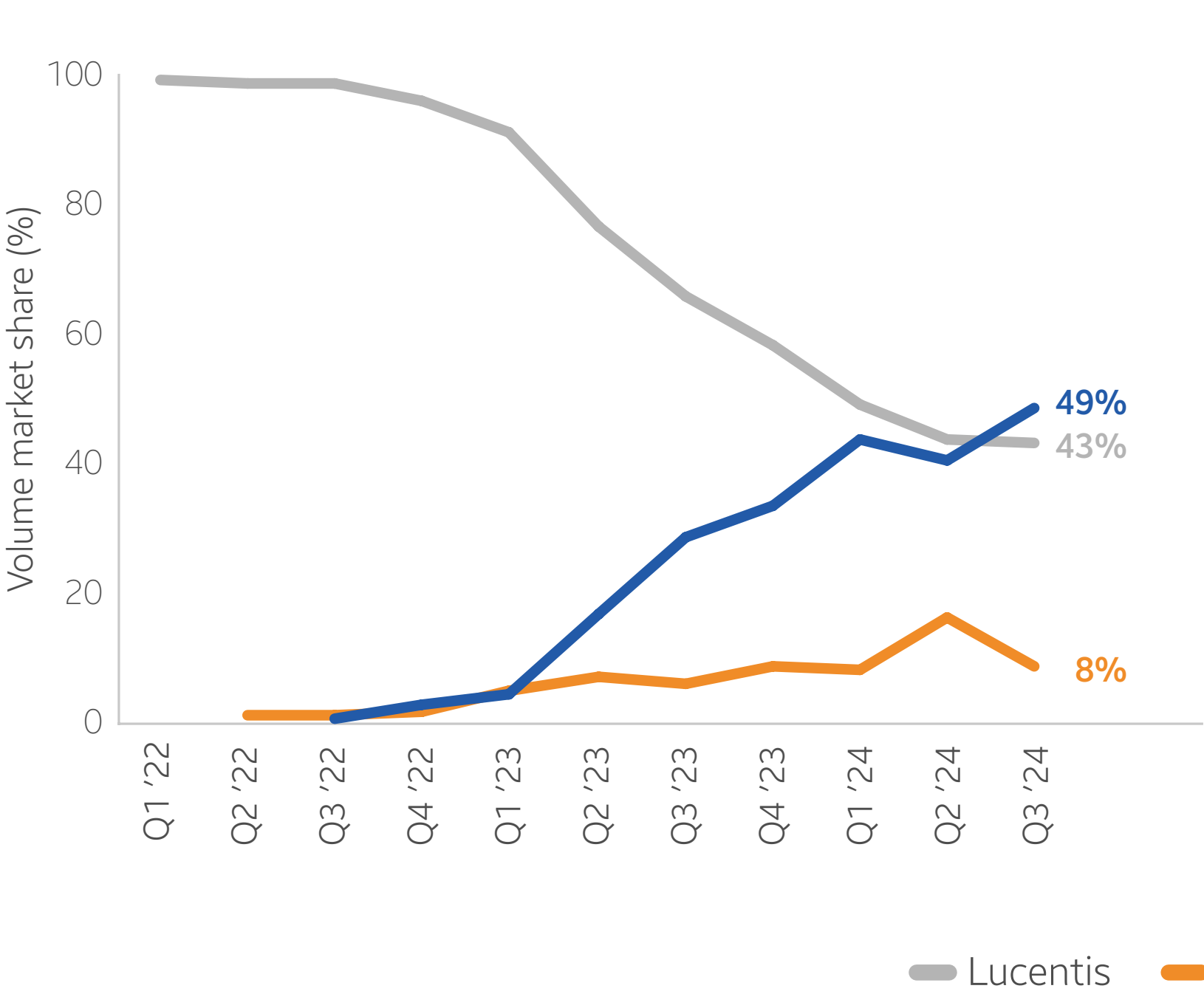
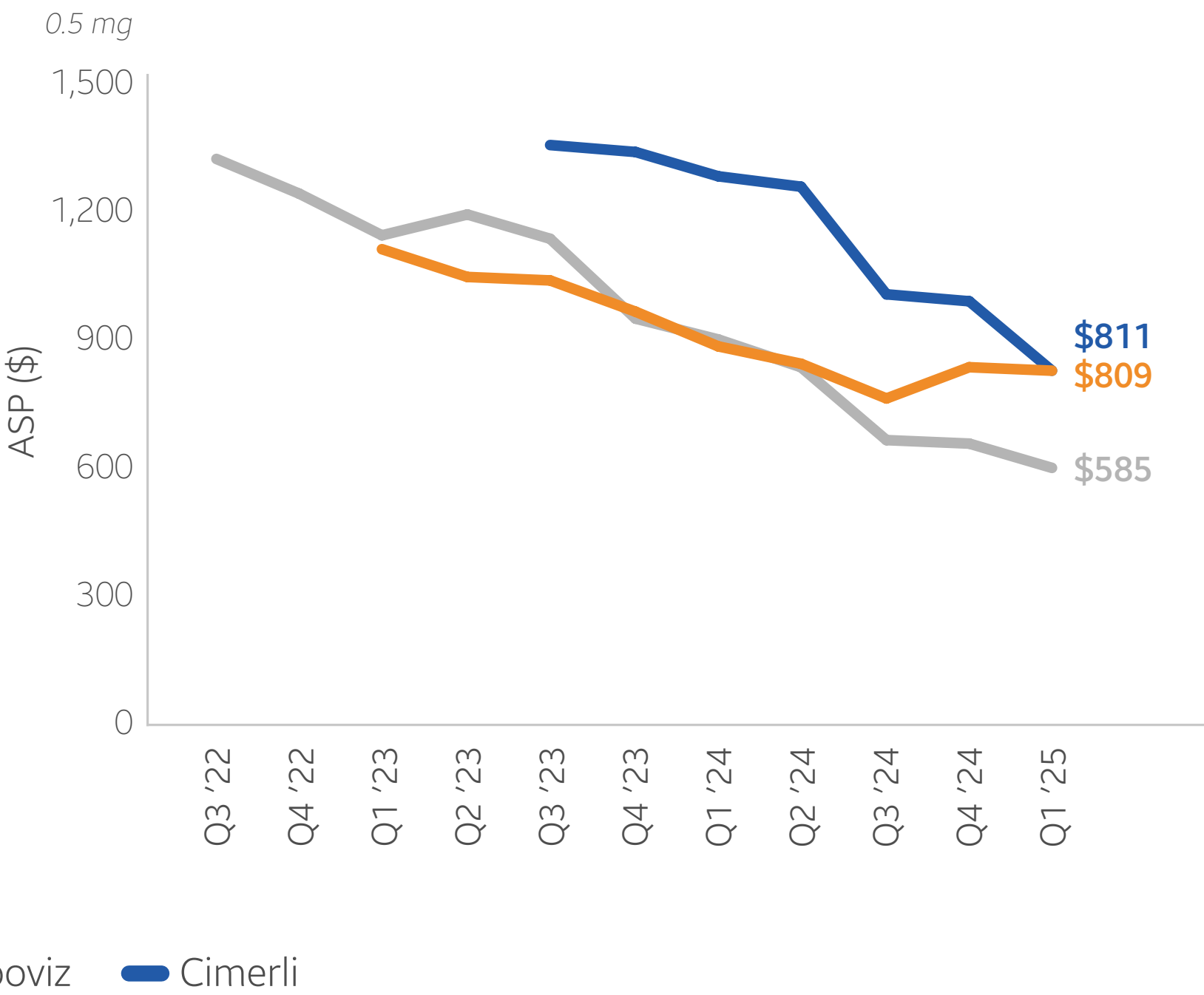


Figure 30. Ranibizumab ASP Trend<sup>3</sup>



Legends are listed in order of launch  
ASP: Average Sales Price



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## IV. Biosimilar Deep Dive

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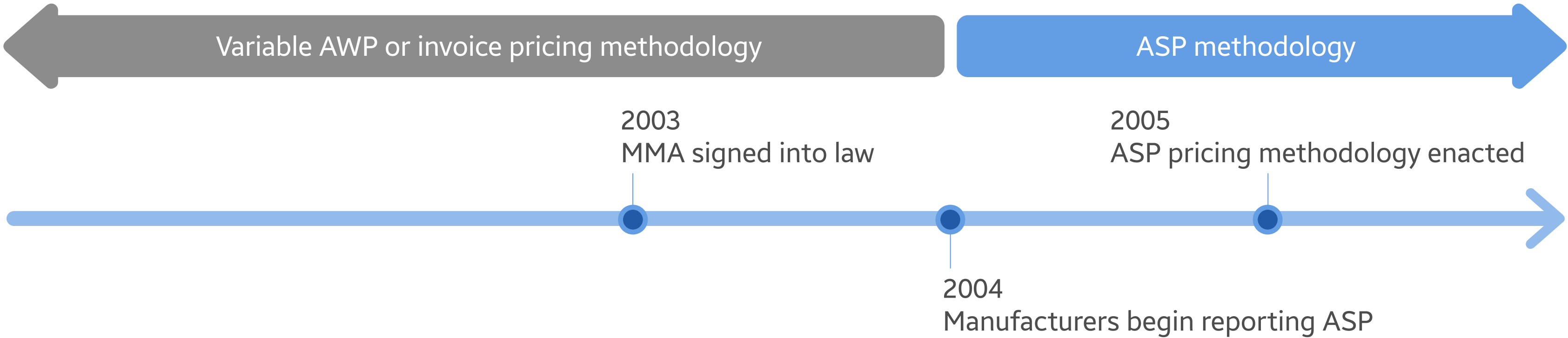
# What is the ASP (Average Sales Price) and why was it developed?

## ASP Regulatory History

- The MMA (Medicare Modernization Act), signed into law in December 2003, established the use of the ASP methodology to standardize Medicare Part B reimbursement for drugs and biologicals.
- Since then, drugs covered by Part B are reimbursed at a rate of **ASP + ASPx6%**, called the MPL (Medicare Payment Limit).
- Prior to the MMA, Part B drugs were generally reimbursed using AWP (Average Wholesale Price) or invoice (from the provider to the payer) methodology.

## ASP Reimbursement

- The 6% provides an add-on payment to providers to cover expenses related to delivering physician-administered drugs. This may include purchase price variability, shipping fees, complex administration, and overhead for storage and handling requirements.
- While ASP and its related MPL is specific to Medicare Part B reimbursement, commercial payers may also utilize a product's MPL to help inform their own reimbursement rates. Generally, ASP + 6% sets a floor for commercial reimbursement.



Biosimilar Price – Medical Benefit

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Biosimilar Price – Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
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- Ophthalmology

# How is ASP calculated?

## Key Concepts

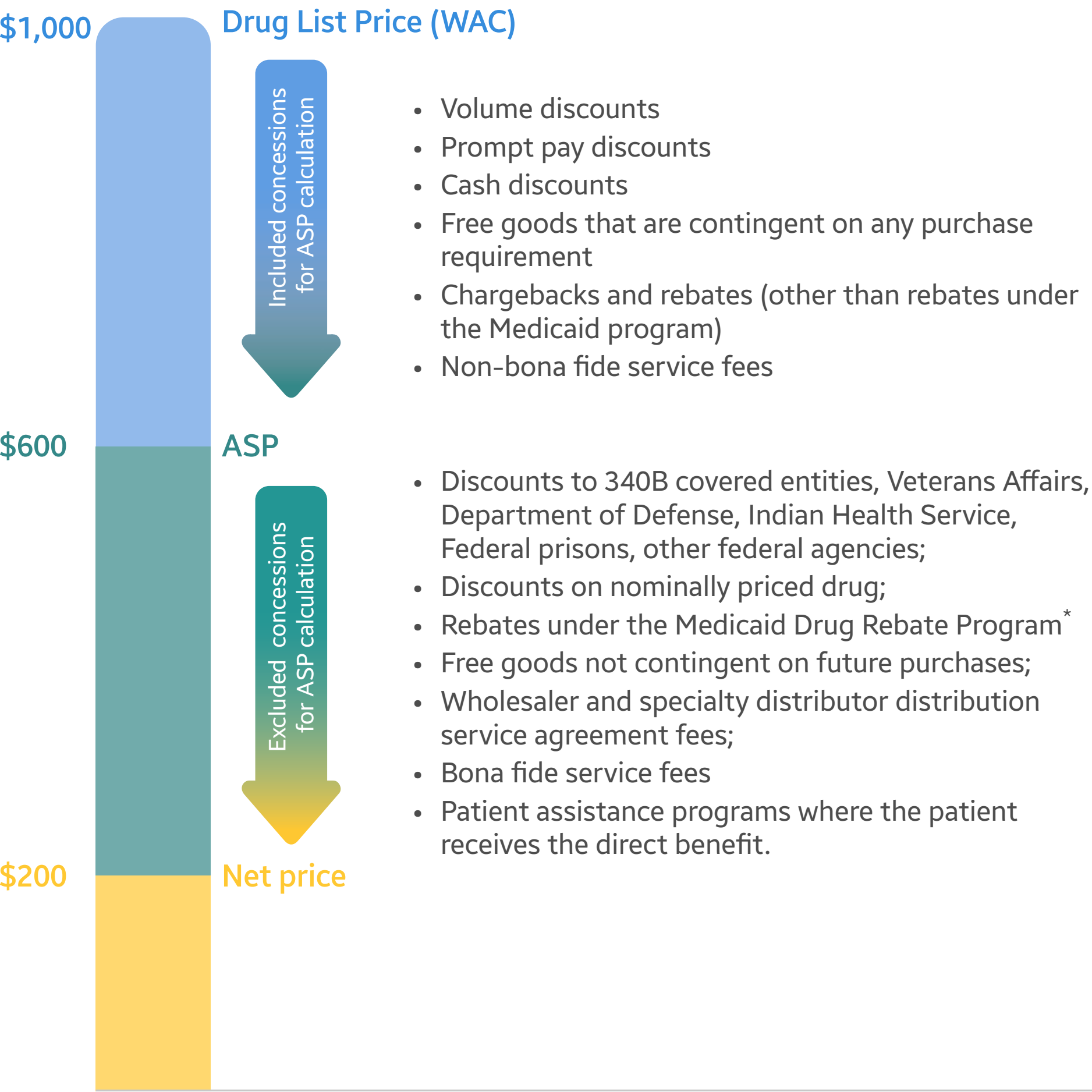
- In order to participate in Medicare Part B, manufacturers are required to report ASP to Centers for Medicare & Medicaid Services (CMS) each quarter.

- ASP is calculated as follows:

$$ASP = \frac{\text{Revenue for units sold in quarter}}{\text{Units sold in quarter}}$$

- However, there are concessions not included in revenue and units when calculating ASP (see right).

## Inclusions and Exclusions in the ASP Calculation



ASP: Average Sales Price CMS: Centers for Medicare & Medicaid Services HCPCS code: Healthcare Common Procedure Coding System code, a standardized coding system used to report medical procedures and services NDC: A National Drug Code, a unique 10-digit number that identifies human drugs in the United States WAC: Wholesale Acquisition Cost

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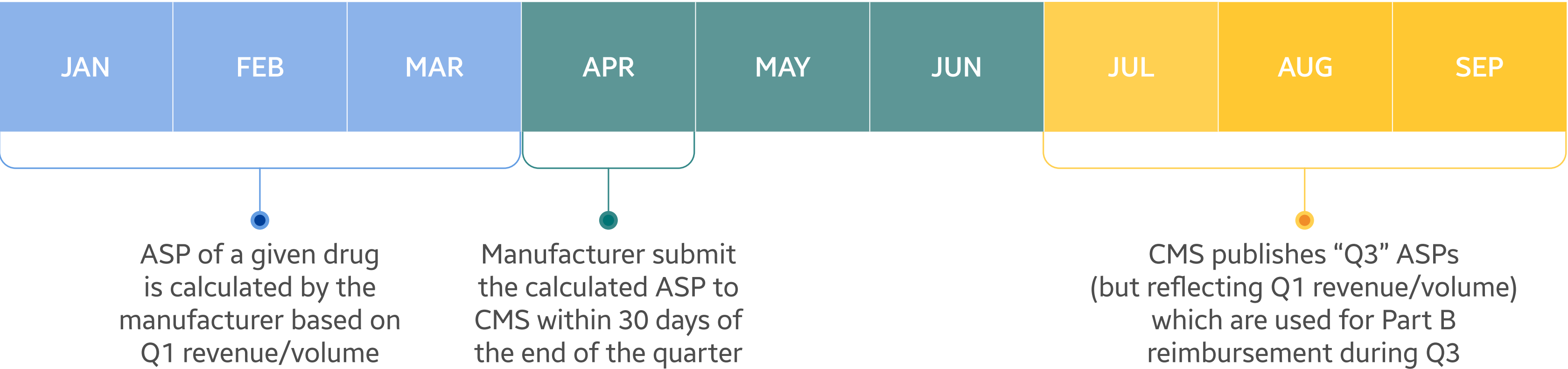
- Immunology & Endocrinology

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# ASP Publication Timing

- There is “two-quarter lag” for ASP reimbursement rate setting.
  - CMS requires manufacturers to submit ASP information to CMS within thirty days after the end of each calendar quarter.
  - For example, sales and discounting data from Q1 is required to be reported to CMS by April 30, and that data is used to set reimbursement rates for Q3.



ASP: Average Sales Price CMS: Centers for Medicare & Medicaid Services

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# What might lead to ASP increases?

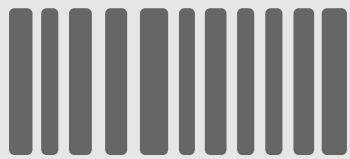
- When tracking ASP data, there are occasions where the ASP may fluctuate from quarter to quarter. In recent quarters, there are several biosimilars where ASP price increases have been observed.
- Below are some theoretical scenarios that could cause an increase in the ASP:



Manufacturer **increases the WAC** price of the product



Manufacturer **decreases contract discounts or rebates** to PBMs, providers, and/or GPOs



A **new NDC** with a new WAC price is introduced into the marketplace

## Changes in the market mix such as:

- Shift in Purchaser Mix:** a higher proportion of sales occurs to entities that receive less discounts
- 340B Program utilization mix:** a higher proportion of sales occurs under the 340B program, where discounts are omitted from the ASP calculation



ASP: Average Sales Price WAC: Acquisition Cost PBM: Pharmacy Benefit Managers GPO: Group Purchasing Organization  
NDC: A National Drug Code, a unique 10-digit number that identifies human drugs in the United States

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# How does ASP based reimbursement impact the biosimilar marketplace?

- Given that Medicare Part B drugs are reimbursed with a percentage-based add-on payment ( $ASP + ASP \times 6\%$ ), there was potential for providers to be incentivized to prescribe and bill for higher cost drugs.
- In order to combat this unintended consequence, CMS payment policy for qualifying biosimilars is based on the **biosimilar ASP plus 6% of the originator’s ASP**.
- CMS went a step further by issuing a temporary payment increase to biosimilars intended to further encourage their adoption. As of October 1, 2022, existing “qualifying biosimilars” are reimbursed at **biosimilar ASP plus 8% of the originator’s ASP**. This temporary payment increase remains in effect for five years and applies to biosimilars with an ASP that is lower than the originator.

Medicare Part B Reimbursement	Originator	Biosimilar	Qualifying Biosimilar (2022-2027) (When ASP is lower than originator)
Medicare Payment Limit	$ASP + (ASP \times 6\%)$	$ASP + (\text{Originator } ASP \times 6\%)$	$ASP + (\text{Originator } ASP \times 8\%)$

Example	Originator	Biosimilar	Qualifying Biosimilar (When ASP is lower than originator)
WAC Price	\$1000	\$750	\$750
ASP	\$800	\$650	\$650
Provider Purchase Price (assumes ASP)	\$800	\$650	\$650
Reimbursement	$\$800 + \$48 = \$848$	$\$650 + \$48 = \$698$	$\$650 + \$64 = \$714$
Provider Revenue (Reimbursement - Provider Purchase Price)	$\$848 - \$800 = \$48$	$\$698 - \$650 = \$48$	$\$714 - \$650 = \$64$

ASP: Average Sales Price   CMS: Centers for Medicare & Medicaid Services

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- Biosimilar Market Adoption & Price Erosion

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- Ophthalmology

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*Based on internal analysis by SAMSUNG BIOEPIS CO., LTD. using data from the following source: IQVIA MIDAS® in Standard Units for the period Jan 2017 – Sep 2024 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.*
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